

Exhibit 98

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY

IN RE:

FOLEY V. AVON PRODUCTS, INC. ET AL.	MID-L-3095-18 AS
FRACE V. BRENNTAG NORTH AMERICA, ET AL.	MID-L-600-18 AS
GATMAITAN V. IMERYS TALC AMERICA, ET AL.	MID-L-4252-18 AS
GRABOWSKI V. BRENNTAG NORTH AMERICA, ET AL.	MID-L-6805-16 AS
GREENE V. BRENNTAG NORTH AMERICA, ET AL.	MID-L-2456-18 AS
GRIFFIN V. CYPRUS AMAX MINERALS COMPANY, ET AL.	MID-L-4826-18 AS
HODJERA V. BORGWARNER MORSE TEC, LLC, ET AL.	MID-L-5368-17 AS
MCNEILL-GEORGE V. BRENNTAG NORTH AMERICA, ET AL.	MID-L-7049-16 AS
SELVAGGIO V. BRENNTAG NORTH AMERICA, ET AL.	MID-L-598-18 AS
WENDOWSKI V. IMERYS TALC AMERICA, INC., ET AL.	MID-L-6635-17 AS

VIDEOTAPE DEPOSITION OF SUSAN NICHOLSON, MD

Transcript of the deposition of the witness,
called for Oral Examination in the above-captioned
matter, said deposition being taken pursuant to
Superior Court Rules of Practice and Procedure by and
before MARC BRODY, a Notary Public and Certified
Court Reporter of the State of New Jersey, at the law
offices of DRINKER, BIDDLE & REATH, 105 College Road East,
Princeton, New Jersey, on Tuesday, February 19, 2019,
commencing at approximately 10:00 in the forenoon.

BRODY DEPOSITION SERVICES
235 East Broad Street, Suite 1
Westfield, New Jersey 07090

Phone: 908-789-2000 Fax: 908-789-2007

Brody Deposition Services

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1 APPEARANCES:			1 INDEX		
2 COHEN, PLACITELLA & ROTH, P.C.			2 WITNESS PAGE		
3 127 Maple Avenue			3 SUSAN NICHOLSON, MD		
4 Red Bank, New Jersey 07701			4 Direct by Mr. Placitella 5		
5 732-747-9003			6		
6 BY: CHRISTOPHER PLACITELLA, ESQ.			7		
7 AND: DENNIS GEIER, ESQ.			8		
8 Attorneys for Plaintiff			9		
9 RAWLE & HENDERSON, LLP (Via speakerphone)			10		
10 1339 Chestnut Street, 16th floor			11 EXHIBITS		
11 Philadelphia, Pennsylvania 19107			12 NO. DESCRIPTION PAGE		
12 215-575-4200			13 P-1 Deposition Notice 5		
13 BY: ANISHA S. ABRAHAM, ESQ.			14 P-2 5 pages of notes by S. Nicholson 10		
14 Attorneys for Defendants, Imerys Talc,			15 P-3 Notebook of J&J Documents 54		
15 Cyprus Amax Minerals			16 P-4 Notebook of J&J Documents 54		
16 McGIVNEY, KLUGER & COOK, P.C. (Via speakerphone)			17 P-5 Notebook of J&J Documents 54		
17 18 Columbia Turnpike, 3rd floor			18		
18 Florham Park, New Jersey 07932			19		
19 973-822-1110			20		
20 BY: ELIZABETH BARNA, ESQ.			21		
21 Attorneys for Defendant, Whittaker, Clark &			22 Note: ALL DOCUMENTS REFERRED TO DURING DEPOSITION		
22 Daniels			23 ARE LISTED ON PAGES 201-202.		
23			24		
24			25		
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1 APPEARANCES (Cont'd):			1 MR. PLACITELLA: Mark this P-1.		
2			2 (The above notice is marked P-1.)		
3 O'TOOLE, FERNANDEZ, WEINER & VAN LIEU (Via speakerphone)			3		
4 14 Village Park Road			4 THE VIDEOGRAPHER: We are now on the		
5 Cedar Grove, New Jersey 07009			5 record. My name is Erik Davidson representing		
6 973-239-5700			6 Dynamic Evidence. The date is Tuesday, February 19,		
7 BY: LESLIE LOMBARDY, ESQ.			7 2019 and the time is approximately 10:00 a.m. The		
8 Attorneys for Defendant, Colgate-Palmolive			8 appearances will be noted on the stenographic		
9			9 record.		
10			10 Our court reporter, Marc Brody, will now		
11 ALSO PRESENT:			12 swear in the witness.		
12 Carolyn McNelis, Paralegal, Cohen Placitella & Roth, PC			13 SUSAN NICHOLSON, sworn.		
13 Erik Davidson, Videographer, Dynamic Evidence			14		
15			15 DIRECT EXAMINATION BY MR. PLACITELLA:		
16			17 Q Good morning, Dr. Nicholson, how are you?		
17			18 A Good thanks. Good morning.		
18			19 Q You are a doctor by training. Is that		
19 correct?			20		
20			21 A Yes, a medical doctor.		
21			22 Q When did you graduate medical and from		
22			23 where?		
23			24 A 1992 from the University of		
24			25 Pittsburgh.		
25					

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<p>1 Q Am I correct that you have never, as a 2 medical doctor, you have never seen any actual 3 patients?</p> <p>4 A That's not correct.</p> <p>5 Q When is the last time you actually saw a 6 patient as a medical doctor?</p> <p>7 A I don't have a precise date. For ten 8 years I was a rounding consulting physician at 9 Cornell New York Hospital in New York City, and my 10 activities petered out -- I probably haven't seen a 11 patient in ten years.</p> <p>12 Q You started at Johnson and Johnson in 13 2006. Is that correct?</p> <p>14 A That's correct.</p> <p>15 Q In what capacity?</p> <p>16 A As a senior director in clinical research 17 in our pharmaceutical division.</p> <p>18 Q Did you ever have any personal interaction 19 with the FDA concerning the issue of asbestos and 20 talc?</p> <p>21 A No, I didn't.</p> <p>22 Q Am I correct you have no training in 23 geology?</p> <p>24 A That's correct.</p> <p>25 Q And you are not an expert in testing talc</p>	<p>1 Q And the documents you reviewed, 2 specifically are what?</p> <p>3 A I reviewed documents specifically going 4 back and forth between Johnson and Johnson to the 5 FDA, the FDA back to Johnson and Johnson and 6 documents from the industry group CTFA, now PCPC 7 relating to talc and asbestos testing as they were 8 acting on behalf of the industry as general 9 background, and also some of the contextual 10 documents for those decades. It has been 50 years 11 of communications and an evolution of science, so 12 some contextual documents were necessary to 13 understand the context.</p> <p>14 Q Am I correct that those documents are with 15 you today?</p> <p>16 A They are.</p> <p>17 Q We will mark them at a break so not to 18 take up any time.</p> <p>19 Am I correct that you are not the 20 author or the recipient of any of the documents in 21 these books?</p> <p>22 A I'm not specifically, no.</p> <p>23 Q So you were the person designated on 24 behalf of the Johnson and Johnson to speak for the 25 company, but you have no personal knowledge of any</p>
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<p>1 for asbestos?</p> <p>2 A I'm not.</p> <p>3 Q You have in front of you P-1, which is the 4 deposition notice for today. The deposition notice 5 calls for Johnson and Johnson to produce a corporate 6 representative with the most knowledge concerning 7 testing information provided to the Food and Drug 8 Administration by Johnson and Johnson concerning the 9 asbestos content of cosmetic talc, and any responses 10 from the FDA in relation thereto. Do you see that?</p> <p>11 A Yes, I do.</p> <p>12 Q Why are you the person most qualified?</p> <p>13 A I'm the person most qualified because I've 14 reviewed all of the documents related to the 15 communications back and forth between the FDA 16 starting in the late '60s up until the present.</p> <p>17 I have interviewed and interacted 18 with the individuals who currently do the testing, 19 people who are involved historically with the 20 testing, so I understand what was communicated and 21 how the testing methodology evolved over time.</p> <p>22 Q Any people still work for Johnson and 23 Johnson who were involved in communicating with the 24 FDA concerning the testing for asbestos in talc?</p> <p>25 A Not that I'm aware of, no.</p>	<p>1 of the evidence you brought with you today?</p> <p>2 A That's not correct. I didn't say that. I 3 was involved in more contemporary communications and 4 discussions about communications with the FDA, but 5 your question previously was about whether or not 6 they were to me specifically or from me 7 specifically. That answer is no.</p> <p>8 But I was involved in discussions 9 related to the communications.</p> <p>10 Q Have you communicated yourself with the 11 FDA either in writing or verbally?</p> <p>12 A I was at a meeting in June of last year 13 with a group of individuals from Johnson and Johnson 14 and the FDA to discuss the quality systems and 15 methods for testing asbestos.</p> <p>16 Q June 19, 2018?</p> <p>17 A Correct.</p> <p>18 Q You said you interviewed. By the way, who 19 made the determination as to what documents you were 20 going to review in preparation for today's 21 deposition?</p> <p>22 A The attorneys assisted in searching the 23 database. It is quite a large and extensive 24 database for FDA communications related to the 25 request for today.</p>

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<p>1 Q So the lawyers made the decision what 2 documents you were going to review?</p> <p>3 A The actual communications, yes. With 4 regard to context, we discussed that and 5 collaborated on which documents were most relevant.</p> <p>6 Q Now, you said you interviewed people in 7 connection with today's deposition. Who was that?</p> <p>8 A I'm going to refer to my notes here, if 9 you don't mind.</p> <p>10 Q Sure.</p> <p>11 MR. PLACITELLA: Why don't we just 12 mark your notes as P-2.</p> <p>13 (Dr. Nicholson's notes are marked 14 P-2.)</p> <p>15 Q Why don't you describe what P-2 is.</p> <p>16 A P-2 are a number of notes during 17 preparation for today. It is a lot of information 18 and I wanted to organize my thinking by decades, 19 '60s, '70s, '80s, '90s, 2000s and 2010 to current.</p> <p>20 In addition, I made some notations 21 about individuals that I would speak to about 22 various topics, and just some contextual notes for 23 my own -- a memoir, if you will.</p> <p>24 Q So who are the people you spoke with?</p> <p>25 A That's what where I was headed. I spoke</p>	<p>1 A Previous conversations I've had with John 2 Hopkins and Don Hicks. Don Hicks is a director of 3 quality. He since retired.</p> <p>4 Q Did John Hopkins have any dealing with the 5 FDA to your knowledge?</p> <p>6 A Yes. He started with the company in 1976 7 and retired in 2000.</p> <p>8 Q You know for a fact he spoke with the FDA 9 about the issue of asbestos and testing?</p> <p>10 A He and I discussed communications back and 11 forth. I don't know that he actually was the person 12 speaking on any given case, but he had the 13 historical knowledge.</p> <p>14 Q But do you know whether or not he had any 15 personal involvement with the FDA?</p> <p>16 A I believe he did, yes.</p> <p>17 Q Now, anybody else?</p> <p>18 A Not that I recall.</p> <p>19 Q I want to talk to you about what Johnson 20 and Johnson understands or understood historically 21 its role was as it related to communications with 22 the FDA.</p> <p>23 Am I correct that Johnson and Johnson 24 understands that cosmetic talc does not require 25 premarket approval from the FDA?</p>
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<p>1 to Linda Szczepaniak.</p> <p>2 Q Spell that for the reporter and me.</p> <p>3 A I wish I could. S C Z and the rest is we 4 will have to -- P H O N I K, maybe.</p> <p>5 Q What was her job?</p> <p>6 A Global head of regulatory affairs for our 7 consumer division.</p> <p>8 Q For what period of time?</p> <p>9 A I don't know when she started. At least 10 four years.</p> <p>11 Q Currently?</p> <p>12 A That's correct. Currently.</p> <p>13 Q Who else?</p> <p>14 A Bobbette Williams.</p> <p>15 Q Bobbette?</p> <p>16 A Williams.</p> <p>17 Q And what is her job?</p> <p>18 A She's Vice-President in our quality group.</p> <p>19 Q Okay. Who else?</p> <p>20 A I spoke to Tim McCarthy who has been with 21 the company a number of years. He is a 22 toxicologist.</p> <p>23 Q Is he still with the company?</p> <p>24 A He is.</p> <p>25 Q Who else?</p>	<p>1 A Yes.</p> <p>2 Q Am I correct that the FDA promulgated 3 regulations that remain in effect today followed by 4 Johnson and Johnson that require each ingredient 5 used in cosmetic product, any finished cosmetic 6 product be adequately substantiated for safety prior 7 to marketing?</p> <p>8 MR. SMITH: Objection.</p> <p>9 A Yes, we are aware of that.</p> <p>10 Q And is Johnson and Johnson further aware 11 that the regulations state that any ingredient or 12 product whose safety is not adequately substantiated 13 prior to marketing, is misbranded unless it contains 14 the following conspicuous statement on the principal 15 display panel. "Warning, the safety of this product 16 has not been determined."</p> <p>17 MR. SMITH: Objection.</p> <p>18 Q Are you aware of that?</p> <p>19 MR. SMITH: Could I just ask you to 20 put a little pause in there before you answer so I 21 can pipe in once in a while and earn my fee?</p> <p>22 A Yes.</p> <p>23 Q Johnson and Johnson understood that a 24 manufacturer who has not adequately substantiated 25 the safety of their cosmetic product or their</p>

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<p>1 ingredients cannot ship their product in interstate 2 commerce?</p> <p>3 MR. SMITH: Objection.</p> <p>4 A Yes.</p> <p>5 Q In addition, a manufacturer of a cosmetic 6 product must assure that the cosmetic label shall 7 bear a warning statement whenever necessary or 8 appropriate to prevent a health hazard that may be 9 associated with the product?</p> <p>10 MR. SMITH: Objection.</p> <p>11 A Yes.</p> <p>12 Q Johnson and Johnson understands that the 13 regulations require that an ingredient or product 14 having a history of use in or as a cosmetic may at 15 any time have its safety brought into question by 16 new information that in and of itself is not 17 conclusive?</p> <p>18 MR. SMITH: Objection.</p> <p>19 A I don't know what that means.</p> <p>20 Q It is not proven beyond more probable than not. Just the risk is there.</p> <p>21 A Can you repeat?</p> <p>22 Q Sure the regulations require that an ingredient or product having a history of use as a cosmetic may at any time have its safety brought</p>	<p>1 the scope.</p> <p>2 MR. PLACITELLA: You can make that 3 objection. I think it is not proper, but you can 4 make it. If you have a form objection, that's what 5 is permitted. You can raise scope with the judge. 6 I think it is clearly within the scope.</p> <p>7 MR. SMITH: Again, I know we are not 8 going to figure that out today. I want to make sure 9 we are all on the same page. Do you want me to put 10 the basis for the objection on the record?</p> <p>11 MR. PLACITELLA: That's fine, the way 12 you are --</p> <p>13 MR. SMITH: Just objection preserves 14 everything so we can keep --</p> <p>15 MR. PLACITELLA: Fair enough.</p> <p>16 Q Johnson and Johnson understands that a 17 cosmetic is considered adulterated if it bears or 18 contains any poisonous or deleterious substance 19 which may render it injurious to users?</p> <p>20 MR. SMITH: Objection.</p> <p>21 A Yes.</p> <p>22 Q Johnson and Johnson understands that information provided to the FDA concerning the testing of Johnson and Johnson talc is voluntary,</p>
Page 15	Page 17
<p>1 into question by new information that in itself is 2 not conclusive?</p> <p>3 MR. SMITH: Objection.</p> <p>4 Q You understood that?</p> <p>5 A I understand that. I didn't understand. I 6 hear you, but that last piece, I'm not sure what 7 that means.</p> <p>8 But let me just say we do understand 9 that the safety of products are overseen on a 10 continuous basis, and if there's new information 11 that comes in, that calls into question the safety 12 of a product that, yes, we are obligated to research 13 that, understand it, determine if there's been any 14 change in the safety profile that's actionable, if 15 that's your question, yes.</p> <p>16 MR. SMITH: While there's no question 17 bending, let me put on the record my understanding, 18 as we discussed before we started the deposition 19 with opposing counsel, placing the word objection on the record preserves all bases?</p> <p>21 MR. PLACITELLA: You could say 22 objection to form, if that is your objection.</p> <p>23 MR. SMITH: I'm objecting to beyond 24 the scope. This witness is here as a 30(b)(6). She 25 is being asked questions that in my view are outside</p>	<p>1 correct?</p> <p>2 MR. SMITH: Objection.</p> <p>3 A Yes.</p> <p>4 Q Johnson and Johnson understands that without a regulation, the FDA has no authority to require information on safety testing related to talc from Johnson and Johnson, correct?</p> <p>5 MR. SMITH: Objection.</p> <p>6 A I'm not sure that's correct. If the FDA has a concern about safety and they ask us for information, I believe we are obligated to give it to them.</p> <p>7 Q Okay. Johnson and Johnson understands now and historically that the FDA only has very limited resources to commit to cosmetic product review, monitoring or safety?</p> <p>8 MR. SMITH: Objection.</p> <p>9 A I can't speak to the resources of the FDA.</p> <p>10 Q Have you looked at documents that in fact indicate that the FDA has limited resources on the issue of talc testing and asbestos? You are aware of that, aren't you?</p> <p>11 A I know there's one document that makes reference to that at a point in time about a very extensive testing program that was discussed. I</p>

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<p>1 don't think that's a general statement that's 2 applicable to the FDA.</p> <p>3 Q So it is your position that the FDA has 4 more than adequate resources to do its own testing 5 of the Johnson and Johnson talc for asbestos?</p> <p>6 MR. SMITH: Objection.</p> <p>7 A I'm not in a position to comment on the 8 FDA's resources.</p> <p>9 Q Does Johnson and Johnson agree that the 10 FDA regulatory authority over cosmetics is less 11 comprehensive than over food and drugs?</p> <p>12 MR. SMITH: Objection.</p> <p>13 A I'm aware of that, yes.</p> <p>14 Q Does Johnson and Johnson understand that 15 in its oversight of the cosmetic industry, the FDA 16 must rely on part on voluntary industry cooperation?</p> <p>17 MR. SMITH: Objection.</p> <p>18 A Yes, I understand that.</p> <p>19 Q Does Johnson and Johnson understand that 20 the FDA does not have authority to require Johnson 21 and Johnson to do safety testing and provide injury 22 reports concerning its talc?</p> <p>23 MR. SMITH: Objection.</p> <p>24 A I can't agree that we understand that in 25 totality. If the FDA made a specific request for</p>	<p>1 Q And is that something that was established 2 by the cosmetic trade association as far back as 3 1976?</p> <p>4 A I don't remember the specific historical 5 details.</p> <p>6 Q You don't know who was responsible for 7 forming the CIR?</p> <p>8 A Exactly.</p> <p>9 Q Or what entity?</p> <p>10 A Exactly, no, I'm not.</p> <p>11 Q Do you know that the CIR is an industry 12 funded panel that reviews the safety of ingredients 13 used in cosmetic talc?</p> <p>14 MR. SMITH: Objection.</p> <p>15 A I know they get funding from the industry, 16 yes.</p> <p>17 Q Am I correct that the purpose of the CIR 18 is to determine cosmetic ingredients for which 19 there's reasonable certainty in the judgment of 20 competent scientists that the ingredient is safe 21 under the conditions of use?</p> <p>22 MR. SMITH: Objection.</p> <p>23 A Yes.</p> <p>24 Q Has the CIR in fact stated that safe or 25 safety means there's no evidence in the available</p>
Page 19	Page 21
<p>1 information, I believe we would be obligated to 2 respond to it.</p> <p>3 We don't regularly and routinely 4 share safety information with the FDA, unless it is 5 required, or we feel that it is important and 6 helpful.</p> <p>7 Q Does Johnson and Johnson agree that a 8 cosmetic manufacturer has a responsibility to 9 substantiate the safety of their product or they 10 must warn consumers the safety of the product has 11 not been determined?</p> <p>12 MR. SMITH: Objection.</p> <p>13 A Yes.</p> <p>14 Q Does Johnson and Johnson understand that 15 if there's a health hazard associated with the product, 16 it must include a warning on that product?</p> <p>17 MR. SMITH: Objection.</p> <p>18 A Yes.</p> <p>19 Q Do you know what the Cosmetic Ingredient 20 Review or CIR is?</p> <p>21 A Yes.</p> <p>22 Q What is that?</p> <p>23 A The Cosmetic Ingredient Review is a 24 process and a system essentially of reviewing the 25 safety of cosmetic ingredients.</p>	<p>1 information that demonstrates or suggests reasonable 2 grounds to suspect a hazard to the public under the 3 conditions of use that are now current or that might 4 reasonably be expected in the future?</p> <p>5 MR. SMITH: Objection.</p> <p>6 A I can't answer that because I haven't 7 reviewed CIR's definitions as of the recent 8 past.</p> <p>9 Q How much work did you do in reference to 10 the CIR to prepare for today's deposition?</p> <p>11 A None.</p> <p>12 Q None at all?</p> <p>13 A No.</p> <p>14 Q Does Johnson and Johnson agree that it has 15 a responsibility to assure that there's reasonable 16 certainty there's no evidence to suspect that their 17 cosmetic talc products may cause any harm to the 18 consumer?</p> <p>19 MR. SMITH: Objection.</p> <p>20 A Could you repeat that?</p> <p>21 Q Does Johnson and Johnson recognize it has 22 a responsibility to assure that there's reasonable 23 certainty that there is no evidence to suspect that 24 their cosmetic talc products may cause harm to the 25 consumer?</p>

Page 22	Page 24
<p>1 MR. SMITH: Objection.</p> <p>2 A Yes.</p> <p>3 Q Does Johnson and Johnson recognize that if 4 there is evidence that there are reasonable grounds 5 to suspect that the cosmetic talc product may cause 6 harm for the proposed use, such product does not 7 meet industry standards for safety?</p> <p>8 MR. SMITH: Objection.</p> <p>9 A Yes.</p> <p>10 Q Does Johnson and Johnson recognize that 11 talc with asbestos fibers are recognized as known 12 human carcinogens?</p> <p>13 MR. SMITH: Objection.</p> <p>14 A Asbestos is a known carcinogen, yes.</p> <p>15 Q And Johnson and Johnson recognizes that if 16 asbestos or asbestos fibers are found in the 17 talcum powder products, those products would be 18 adulterated under the Federal Food Drug and Cosmetic 19 Act?</p> <p>20 MR. SMITH: Objection.</p> <p>21 A To clarify, if there's asbestos in talc, 22 yes, I would agree.</p> <p>23 Q Am I correct, and I asked you this before, 24 but I want to tease it out a little bit. Is it 25 Johnson and Johnson's position that it is not aware</p>	<p>1 numbers.</p> <p>2 MR. PLACITELLA: It was given to me 3 by Dr. Hopkins in his deposition. It was marked 4 at his deposition as D-12, so that's your issue.</p> <p>5 Q Do you see where it talks about a program, 6 the first thing says cosmetics. Do you see that?</p> <p>7 A Yes.</p> <p>8 Q If you flip through it, you see that it 9 refers to multiple years and multiple projects. Do 10 you see that?</p> <p>11 A I do.</p> <p>12 Q I'm going to refer you to the entry for 13 1976. I'll blow it up for you. Under the project 14 titled Determination of Asbestos in Talc. Do you 15 see that?</p> <p>16 MR. SMITH: What page are we on, 17 Counsel?</p> <p>18 A I need to look at it.</p> <p>19 Q Your pages aren't numbered, unfortunately.</p> <p>20 MR. SMITH: Some are.</p> <p>21 Q Project number 00679.</p> <p>22 MR. SMITH: There are multiple pages 23 with that project.</p> <p>24 Q There are multiple pages and I'm on the 25 page that talks about description of this quarter's</p>
<p>1 that FDA has limited resources when it comes to 2 testing cosmetic talc for asbestos?</p> <p>3 MR. SMITH: Objection.</p> <p>4 A I can't speak to the FDA'S resources.</p> <p>5 Q Do you know who John Stuart is, who worked 6 at the FDA?</p> <p>7 A I don't recall off the top of my head, no.</p> <p>8 The name sounds familiar, but I don't remember 9 exactly.</p> <p>10 Q Do you know that John Stuart left the FDA 11 in 1976?</p> <p>12 A No.</p> <p>13 Q Do you know that when John Stuart left the 14 FDA, there was no one at FDA any experience in 15 testing talc for asbestos?</p> <p>16 MR. SMITH: Objection.</p> <p>17 A I can't speak to FDA'S expertise or 18 resources.</p> <p>19 Q D-12 is a document from 1975 that was 20 provided to me by Dr. Hopkins at his deposition. 21 Has Dr. Hopkins shared this document with you?</p> <p>22 A I don't recall seeing this. It refers to 23 aerosols and hair preparations.</p> <p>24 MR. SMITH: Counsel, while there's no 25 question pending, this document doesn't have Bates</p>	<p>1 activities, and the first paragraph stating, the 2 purpose of this project is to develop one or several 3 methods for sufficient sensitivity and reliability 4 which will permit the determination of asbestos and 5 other contaminants in talc-containing products with 6 the necessary degree of accuracy and at a 7 concentration at which such contaminants present a 8 potential health hazard. Do you see that?</p> <p>9 MR. SMITH: I don't.</p> <p>10 A Yes.</p> <p>11 Q When you met with, when you spoke with Dr. 12 Hopkins, he didn't discuss any of these reports with 13 you, even though they refer directly to the FDA --</p> <p>14 MR. SMITH: Objection.</p> <p>15 Q In testing of asbestos?</p> <p>16 A Let me point out, number one, that this 17 starts with aerosols and hair preparations. Number 18 two, this doesn't look like a communication to or 19 from Johnson and Johnson to the FDA, so I did not 20 review that in preparation for today. And this is a 21 bit of a confusing document. I'm not exactly sure 22 what we are supposed to focus on since every page 23 seemed to be marked project 679.</p> <p>24 Q What we are focusing on the page that 25 talks about the determination of asbestos in talc.</p>
<p>1</p> <p>2</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1</p> <p>2</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

<p style="text-align: center;">Page 26</p> <p>1 A Yes, I realize that. 2 Q And what is listed in this document, and 3 this came from Johnson and Johnson. I didn't get it 4 on my own. You understand that, right? 5 A That's fair. I'm just trying to find the 6 page you are on. 7 MR. SMITH: In fairness, I don't know 8 that it came from Johnson and Johnson. 9 MR. PLACITELLA: You don't know? 10 MR. SMITH: It doesn't have Johnson 11 and Johnson Bates numbers on it. 12 MR. PLACITELLA: Mr. Hicks is the one 13 who brought it to a deposition and went over it. 14 MR. SMITH: I don't quarrel. It may 15 have come from the FDA. I don't know. 16 Q Do you see where it says, "Due to 17 separation of John Stuart from government service, 18 no methods development investigations were done 19 during the first quarter of 1976." Do you see that? 20 A I do see that. 21 Q If you go to the next page, it states, 22 "Due to lack of specialized personnel in certain 23 necessary instrumentation, no significant work was 24 done on methods developments during the second 25 quarter of '76." Do you see that?</p>	<p style="text-align: center;">Page 28</p> <p>1 testing itself on Vermont talcs? 2 A Well, I'm aware of FDA doing testing 3 multiple times. Several times during the '70s, in 4 the '80s, 2009 testing cosmetic talc products, 5 including testing of raw materials, and some of 6 those would have been from the Vermont mines. 7 The exact dates of when they tested 8 materials that came from the Vermont mines, I cannot 9 speak to that exactly. 10 Q So you don't know when the last time the 11 FDA personnel was involved in testing talc from the 12 Vermont mine? 13 MR. SMITH: Objection. 14 Q Correct? 15 A What I just said, if there's material that 16 came out of Vermont and was some in some of those 17 cosmetic talcs that were tested several times 18 in the '70s, in the '80s and 2009. I don't know 19 that there was an exact date that FDA stopped 20 testing Vermont talc because I don't know if there's 21 Vermont talc in those samples that were tested in 22 2009. 23 Q As you sit here today, you can't point to 24 a single test done by the FDA itself on Vermont talc 25 after 1979, correct?</p>
<p style="text-align: center;">Page 27</p> <p>1 A I do. 2 Q Do you see where it says, "Because of 3 limited resources and in regard to instrumentation 4 and trained personnel, the only project plan 5 relating to the methods development and sample 6 enrichment floatation in order to detect lower 7 levels of certainty by DPA." Do you see that? 8 A I do. 9 Q Now, you are aware, are you not, that the 10 FDA has done no testing on Vermont talc since 1979 11 itself? You know that, correct? 12 MR. SMITH: Objection. 13 A I don't know the exact dates of testing 14 that's been done, but there are multiple 15 publications and test reports related to the Vermont 16 mines. 17 Q I'm asking you whether you know from your 18 preparation and review of the documents in your 19 possession that the FDA had itself its own 20 personnel, has done no testing on any Vermont talc 21 since 1979? 22 MR. SMITH: Objection. 23 A I'm not aware of what dates they did 24 Vermont testing. 25 Q Do you know if the FDA ever did any</p>	<p style="text-align: center;">Page 29</p> <p>1 MR. SMITH: Objection. 2 A So again, there was a survey of cosmetic 3 talcs done in 2009. Multiple samples that were 4 used. I don't know the origin of all of those 5 cosmetic products. They not Johnson and Johnson 6 products. It is possible they may have been from of 7 the Vermont mine, but I can't speak to that 8 directly. 9 Q What was my question? 10 MR. SMITH: Objection. 11 A Your question was when was the last date 12 did FDA test Vermont talc after 1979. And as I 13 said, they tested in the '80s, and again in 2009. 14 It is possible some of that material came from the 15 Vermont mine. 16 Q Ma'am, here is my question, please. As 17 you sit here today, you have no evidence in front of 18 you to indicate that the FDA itself ever did any 19 testing of talc from the Vermont mine after 1979, 20 correct? 21 A As I -- 22 MR. SMITH: Objection. 23 A As I said, there are multiple surveys that 24 were done. 25 Q I'm not asking you about multiple surveys.</p>

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1 Please, I'm asking you specifically -- 2 MR SMITH: You can't talk over the 3 witness. 4 MR. PLACITELLA: I can talk over the 5 witness if she refuses to answer the question. 6 MR. SMITH: She is not refusing to 7 answer the question. 8 MR. PLACITELLA: I'll withdraw the 9 question. 10 MR. SMITH: Okay. Question 11 withdrawn. 12 Q Do you believe an honest and forthright 13 witness can provide a simple answer to a simple 14 question? 15 MR. SMITH: Objection. 16 A If there's a simple answer, yes. If 17 there's not a direct answer to your question, I'll 18 give you the related information. 19 Q Ma'am, can you show me in any of the books 20 that you have in front of you today any testing done 21 by the FDA of Vermont source talc after 1979? Show 22 it to me. 23 A I would be happy to review the results 24 from the 1986 survey that was done by FDA and I'll 25 be happy to review the 2009 results from the FDA.	1 the provenance of the samples they tested in 1986 2 and in 2009. 3 Q So you don't know as you sit here today 4 that the FDA ever performed any tests on Vermont 5 mines after 1979? You don't know that, true? 6 MR. SMITH: Objection. 7 A What I know is the FDA did testing in 1986 8 and in 2009. I don't know the provenance of those 9 cosmetic samples because they are not J and J 10 samples of cosmetic material. They may have come 11 from the Vermont mine. I don't know for sure. They 12 are not Johnson and Johnson products. 13 Q Let me ask you the question this way. Do 14 you have any evidence as you sit here today that the 15 FDA ever tested a Johnson and Johnson product after 16 1979 that was sourced from the Vermont mine? 17 A Well, I'll have to check and see when we 18 sourced material from the Vermont mine. 19 Q Yes, Ma'am. Go ahead. 20 A Maybe we can go to the 1986 test results. 21 MR. SMITH: Go to whatever you need 22 to go to. 23 Q Can you tell me what exhibit you are 24 looking at first? 25 A This will be the 1986.
1 As I said, I don't know the source of 2 that talc. It is not all Johnson and Johnson talc. 3 It may have come from Vermont. 4 Q But you don't know? 5 A As I said, I don't know specifically if 6 those cosmetic products tested in '86 and in 2009 7 came from the Vermont mine, but testing was done by 8 FDA in those two periods. 9 You asked me did the FDA test after 10 1979. Maybe. I don't know the provenance of those 11 cosmetic samples that came from those other 12 companies. 13 Q Ma'am, with all due respect, as you sit 14 here today, you can't point me to any evidence that 15 demonstrates that the FDA tested Vermont talc after 16 1979, can you? 17 MR. SMITH: Objection. 18 Q True? 19 MR. SMITH: Objection. 20 A As I said, the FDA has tested in '86 and 21 again in 2009. I don't know if that cosmetic 22 material that came from other companies was from 23 Vermont or not, but FDA did do testing. 24 So again, I don't know if they tested 25 from the Vermont mines or not because I don't know	1 Q The marking on the exhibit for the folder. 2 A It says D-237. I don't know what you mean 3 by the marking. 4 Q The binder is marked with an exhibit 5 number, it is not? Look at these and we will mark 6 them at a break. 7 A This is 1984. November 15, 1984, the 8 Food Additives Valuation Branch did an assessment 9 and review of talcum powder used for cosmetics, 10 which included any relationship to any potential 11 asbestos contamination. 12 I'm looking to see if there's a list 13 here that can tell us what samples -- where the 14 samples came from. 15 Q Why don't we do this. Take a look during 16 the break and we will have everything marked and we 17 will get back to that. 18 A Okay. 19 Q So we are not wasting time. Put a sticker 20 on that so you know to go back to it. 21 A I know exactly where it is. No sticker 22 needed. 23 Q Am I correct that even when Johnson and 24 Johnson provided information to the FDA, Johnson and 25 Johnson controlled what the public could know about

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<p>1 the product safety testing?</p> <p>2 MR. SMITH: Objection.</p> <p>3 A Johnson and Johnson is responsible for 4 whatever is on the packaging of the cosmetic talc 5 products, if that's what you mean, in compliance 6 with the FDA regulations.</p> <p>7 Q No, Ma'am. What I'm asking you is when 8 you gave testing information or reports on your talc 9 to the FDA, you, Johnson and Johnson, were in 10 control of what the FDA could release to the public, 11 correct?</p> <p>12 MR. SMITH: Objection.</p> <p>13 A Well, our communications with the FDA, 14 that's a privileged proprietary information. So 15 that would not be generally publically available.</p> <p>16 I understand people can make a 17 request through the Freedom of Information Act to 18 get redacted information. I don't know the exact 19 process and procedures, but certainly any citizen 20 can make that request.</p> <p>21 Q But whether or not the information is 22 released by the FDA to the citizen making that 23 request is totally within the control of Johnson and 24 Johnson, correct?</p> <p>25 MR. SMITH: Objection.</p>	<p>1 A Mr. Johnston, I don't know.</p> <p>2 Q And Mr. Nashed writes to Mr. Johnston, 3 "Dr. A. Weisler of the Division of Colors and 4 Cosmetics, FDA, informed me today by phone that Dr. 5 Zeitz of the Nader Group has asked him to provide 6 him with information available to them on the talc 7 asbestos question." Do you see that?</p> <p>8 A Yes.</p> <p>9 Q And Dr. Weisler said that Johnson and 10 Johnson had submitted reports at various times, most 11 of them under a confidentiality statement which are 12 not subject to release to the public under the 13 Freedom of Information Act. Do you see that?</p> <p>14 A Yes.</p> <p>15 Q Then he goes on to talk about what he told 16 the FDA. He said, "I told Dr. Weisler that Johnson 17 and Johnson will be happy to discuss release of 18 information if it is deemed helpful to the FDA. 19 However, since our reports include correspondence 20 and opinions from experts, we have submitted such 21 reports with the understanding that they are the 22 exclusive use of the FDA." Do you see that?</p> <p>23 A Yes.</p> <p>24 Q He goes on to state, does he not, that 25 "Unless permission is given, all reports should be</p>
Page 35	Page 37
<p>1 A I don't know that that's true, no.</p> <p>2 Q Do you know that Johnson and Johnson 3 actually stopped information on asbestos testing 4 that it provided to the FDA from being released to 5 the public. You know that, correct?</p> <p>6 MR. SMITH: Objection.</p> <p>7 A I don't know what you are referring to. 8 I'm happy to look at whatever documents you are 9 referring to.</p> <p>10 Q I'm not asking if you are happy to look at 11 documents. You are Johnson and Johnson. I'm asking 12 you, Johnson and Johnson. You, Johnson and Johnson, 13 know that you were controlling exactly what the 14 public could see that you gave to the FDA. You know 15 that you were doing that, correct?</p> <p>16 MR. SMITH: Objection.</p> <p>17 A That's not correct.</p> <p>18 Q Okay. 465 is a memo from Mr. Nashed to 19 D.E. Johnston on June 7, 1973, with subject matter 20 talc asbestos, correct?</p> <p>21 A Yes.</p> <p>22 Q Who are these people, Nashed and Johnston?</p> <p>23 A Dr. Nashed is a J and J employee in our 24 research and development group at this time.</p> <p>25 Q Who is D.E. Johnston?</p>	<p>1 held in confidence by the FDA." Correct?</p> <p>2 A I see that, yes.</p> <p>3 Q 466 is a November 7, 1973 memo from D.R. 4 Pederson. Who is that?</p> <p>5 A I'm not sure.</p> <p>6 Q It is on Johnson and Johnson letterhead?</p> <p>7 A Yes, it is.</p> <p>8 Q What Mr. Pederson writes is, "I want you 9 to be aware that certain material previously 10 provided to the FDA will be released from our 11 confidential disclosure. At that time information 12 was given to the FDA in confidence. We have decided 13 to release that data pertinent to Shower to Shower 14 and Johnson's Medicated Powder, which would dispute 15 the information presented in the Lewin report, 16 recently released by the FDA. We have decided not 17 to release the data either on the Italian mine or on 18 Johnson's Baby Powder and Vermont 66 Talc."</p> <p>19 Correct?</p> <p>20 A I see that, yes.</p> <p>21 Q And you understand that one of the missions 22 of Johnson and Johnson, when it was dealing with the 23 FDA, was to submit rebuttals every time an 24 allegation was made that there was asbestos in the 25 Johnson and Johnson talc, correct?</p>

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<p>1 A Not correct.</p> <p>2 Q And Johnson and Johnson, internally what</p> <p>3 they said they were doing was actually putting out</p> <p>4 fires, right? You have seen that document, correct?</p> <p>5 A You have to show me the document. I don't</p> <p>6 know which document you are referring to.</p> <p>7 Q I'm going to show you what's been marked</p> <p>8 462, and it is entitled Historical Review. Have you</p> <p>9 ever seen this document before?</p> <p>10 A I need a minute to look at it.</p> <p>11 Okay.</p> <p>12 Q I'm looking at the paragraph on the second</p> <p>13 page that talks about when the Food and Drug</p> <p>14 Administration brought talc issue to a head.</p> <p>15 Approximately two years ago, their consultant, Dr.</p> <p>16 Lewin, strongly asserted he had found asbestos in</p> <p>17 Johnson and Johnson powder.</p> <p>18 Johnson and Johnson quickly reacted</p> <p>19 with consultants of their own and after several</p> <p>20 meetings in Washington, Dr. Lewin's original report</p> <p>21 was later amended and he retracted his statements on</p> <p>22 the occurrence of asbestos in Johnson and Johnson</p> <p>23 powder.</p> <p>24 In addition, we have transmitted to</p> <p>25 the FDA formidable rebuttals of any question of the</p>	<p>1 access to FDA officials when safety issues arose</p> <p>2 concerning talc and asbestos, correct?</p> <p>3 A I never heard the term intimate used in</p> <p>4 relation to our relationship with the FDA.</p> <p>5 Q You agree that Johnson and Johnson had a</p> <p>6 far greater access to FDA officials when it came to</p> <p>7 asbestos and talc than an ordinary citizen, correct?</p> <p>8 A That is correct.</p> <p>9 Q And in fact, Johnson and Johnson had a</p> <p>10 greater access than the medical community that was</p> <p>11 in charge of caring for patients hurt by Johnson and</p> <p>12 Johnson when it came to issues of product safety,</p> <p>13 correct?</p> <p>14 MR. SMITH: Objection.</p> <p>15 A Johnson and Johnson did not hurt any</p> <p>16 individuals, so I object to the basis of that</p> <p>17 question.</p> <p>18 Q Let me ask you. Do you agree with me that</p> <p>19 Johnson and Johnson had far greater access to the</p> <p>20 general medical community on issues of asbestos in</p> <p>21 talc, correct?</p> <p>22 MR. SMITH: Objection.</p> <p>23 A Greater access to the medical community?</p> <p>24 I don't know what the question is.</p> <p>25 Q Johnson and Johnson had far greater access</p>
Page 39	Page 41
<p>1 Occurrence of chrysotile in Johnson and Johnson</p> <p>2 powder. Do you see that?</p> <p>3 A I do.</p> <p>4 Q Do you see on the next page where it talks</p> <p>5 about Johnson and Johnson is putting out fires with</p> <p>6 respect to the specific question of asbestos in</p> <p>7 talc?</p> <p>8 A I see that.</p> <p>9 Q Now, am I correct that Johnson and Johnson</p> <p>10 had intimate access to FDA officials when product</p> <p>11 safety issues arose concerning talc?</p> <p>12 A So the documents you are showing me are</p> <p>13 from the '70s.</p> <p>14 Q That's not my question. I'm not asking</p> <p>15 about these documents. I'm asking you another</p> <p>16 question. So listen to it.</p> <p>17 MR. SMITH: Objection to the</p> <p>18 question. If you are not withdrawing it, she is</p> <p>19 going to finish her answer.</p> <p>20 MR. PLACITELLA: No, I'll withdraw it</p> <p>21 and I'll ask it again.</p> <p>22 Q I'm not asking you about the documents</p> <p>23 we just went through. I'm asking you a different</p> <p>24 question.</p> <p>25 Johnson and Johnson had intimate</p>	<p>1 to the FDA officials in dealing with issues of</p> <p>2 asbestos in talc than the general medical community</p> <p>3 did, correct?</p> <p>4 MR. SMITH: Objection.</p> <p>5 A Now I understand your question. Yes, we</p> <p>6 are regulated by the FDA, so of course, we have</p> <p>7 regular and structured interactions with the FDA.</p> <p>8 Q You are aware that FDA officials have left</p> <p>9 government service and went to work for Johnson and</p> <p>10 Johnson, correct?</p> <p>11 MR. SMITH: Objection.</p> <p>12 A Yes, I'm aware of that.</p> <p>13 Q And you are aware the FDA officials have</p> <p>14 left government service and went to work for the</p> <p>15 industry trade organization that you are a member</p> <p>16 of, correct?</p> <p>17 MR. SMITH: Objection.</p> <p>18 A Yes, I'm aware of that.</p> <p>19 Q And can you tell me as you sit here today</p> <p>20 which government, former government officials you</p> <p>21 are aware of that went to work for Johnson and</p> <p>22 Johnson, former FDA officials?</p> <p>23 MR. SMITH: Objection.</p> <p>24 A The ones that pops into my mind is Dr. Sam</p> <p>25 Maldonado, who leads our Pediatric Center of</p>

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<p>1 Excellence.</p> <p>2 Q Any other?</p> <p>3 A Michelle McMurry is a physician in our 4 clinical group in our Device Sector.</p> <p>5 Q Any others?</p> <p>6 A I'm sure there's a long list, but I don't 7 know the list.</p> <p>8 Q You are also aware that former executives 9 for Johnson and Johnson went to work for the FDA, 10 correct?</p> <p>11 MR. SMITH: Objection.</p> <p>12 A Yes.</p> <p>13 Q Which former executives of Johnson and 14 Johnson are you aware of that went to work for the 15 FDA?</p> <p>16 A Again, I think Sam Maldonado went to the 17 FDA and then came back to Johnson and Johnson and it 18 is common in the industry for people who work at the 19 FDA for a period of time during their career.</p> <p>20 Q You actually had former executives who 21 worked at Johnson and Johnson and then went to work 22 at the FDA specifically on the issue of talc safety, 23 correct?</p> <p>24 MR. SMITH: Objection.</p> <p>25 A I'm not aware of that, no.</p>	<p>1 leading officials at the FDA involved with the issue 2 of asbestos and talc? You didn't know that?</p> <p>3 MR. SMITH: Objection.</p> <p>4 A I was asked to look at the communications 5 between Johnson and Johnson and the FDA on asbestos 6 testing and talc safety. I didn't look into the 7 background of Mr. Eiermann, so no, I was not aware of 8 that.</p> <p>9 Q So when you were looking at all these 10 documents, you saw documents referencing Mr. Eiermann, 11 correct?</p> <p>12 A Yes, I did.</p> <p>13 Q When you looked at all these documents, no 14 one in all of Johnson and Johnson told you, hey, that 15 guy used to work for us?</p> <p>16 MR. SMITH: Objection.</p> <p>17 Q In fact, was he was one of our executives? 18 No one ever told you that?</p> <p>19 MR. SMITH: Objection.</p> <p>20 A No, and I wouldn't expect that because we 21 were looking at these documents based on the facts 22 and the scientific merit and the context of the 23 documents, not where people came from. That's not 24 relevant.</p> <p>25 Q So it wasn't relevant that the FDA and</p>
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<p>1 Q You are not aware that you had former 2 executives who went to work at the FDA on the issue 3 of asbestos in Johnson and Johnson's powder?</p> <p>4 MR. SMITH: Objection.</p> <p>5 A No.</p> <p>6 Q Take a look at 465. Remember 465 is the 7 memo that talks about Johnson and Johnson giving the 8 FDA permission to release certain information under 9 the Freedom of Information Act. Do you remember 10 that?</p> <p>11 MR. SMITH: Objection.</p> <p>12 A Yes.</p> <p>13 Q Can you look at the bottom paragraph where 14 Mr. Nashed states, "He added that Dr. Eiermann is now 15 on deck and will be taking over as Director of the 16 Division of Cosmetics and that he, himself is 17 phasing out of the area." Do you see that?</p> <p>18 A Yes, I see that.</p> <p>19 Q Did you know Dr. Eiermann was a former 20 Johnson and Johnson executive?</p> <p>21 MR. SMITH: Objection.</p> <p>22 A No, I did not.</p> <p>23 Q So you didn't know in preparing for 24 today's deposition that a former Johnson and Johnson 25 executive actually took control, or was one of the</p>	<p>1 Johnson and Johnson had a revolving door in terms of 2 executives and people working on safety issues? 3 That wasn't relevant to you?</p> <p>4 MR. SMITH: Objection.</p> <p>5 A I disagree with the context of that 6 question.</p> <p>7 Q Well, Ma'am, you didn't think it was 8 important to know that the person who was one of the 9 people in charge of talc safety and asbestos at the 10 FDA was your former executive? You didn't think 11 that was important?</p> <p>12 MR. SMITH: Objection.</p> <p>13 A I don't know of the scope of Mr. Eiermann's 14 job at FDA or the scope of his job at Johnson and 15 Johnson, and there certainly is no revolving door. 16 I really can't speak to that history and what you 17 are implying with your question.</p> <p>18 Q Ma'am, you know that when citizens raised 19 product safety issues with the FDA concerning talc, 20 the first thing the FDA did was pick up the phone 21 and call Johnson and Johnson to give them a heads 22 up. You knew that, right?</p> <p>23 MR. SMITH: Objection.</p> <p>24 A I don't know what you are referring to 25 specifically.</p>

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<p>1 Q Do you know as a general matter that any 2 time a safety issue was raised concerning Johnson 3 and Johnson tale, somebody at the FDA picked up the 4 phone and called Johnson and Johnson to give them a 5 heads up. You know that happened, correct?</p> <p>6 MR. SMITH: Objection.</p> <p>7 A Well, Johnson and Johnson cosmetics are 8 under the regulatory authority of the FDA, so if 9 somebody brought up a safety issue concerning one of 10 our products, it would be appropriate that they 11 reach out to us directly.</p> <p>12 I don't know if they called or sent 13 an email or a letter, but absolutely Johnson and 14 Johnson should be notified.</p> <p>15 Q Right. But they didn't send a letter 16 saying we got this complaint, how do you respond? 17 What they did, your relationship at the FDA was such 18 that if you got a complaint, they picked up the 19 phone and they told you about it first thing, right? 20 That's what happened.</p> <p>21 MR. SMITH: Objection.</p> <p>22 Q That's what happened.</p> <p>23 MR. SMITH: Objection.</p> <p>24 A I don't know that's true.</p> <p>25 Q In fact, you kept a file at Johnson and</p>	<p>1 such, but I have memos related to calls between 2 Johnson and Johnson and the FDA. 3 Q So in preparing for today's deposition the 4 lawyers never gave you access to the FDA call file, 5 correct?</p> <p>6 MR. SMITH: Objection.</p> <p>7 A You are characterizing a file as a call 8 file. I have not heard that terminology.</p> <p>9 Q Can you look at 491, please. 491 is a 10 memo on Johnson and Johnson letterhead dated January 11 4, 1984 and the memo is to the FDA call file. Do 12 you see that?</p> <p>13 A Yes.</p> <p>14 Q And the re: is talc, correct?</p> <p>15 A Yes.</p> <p>16 Q So I'm asking you again, in preparing for 17 today's deposition, the lawyers for Johnson and 18 Johnson, or anybody else at Johnson and Johnson, 19 never gave you access to the complete FDA call file, 20 correct?</p> <p>21 MR. SMITH: Objection.</p> <p>22 A So we don't -- you are asking if I had 23 access to something called a call file. All of the 24 documents are no longer in paper files. They are in 25 digital form in a database, and they were searched</p>
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<p>1 Johnson that was dedicated entirely to phone calls 2 that the FDA gave you in order to give you a heads 3 up, correct?</p> <p>4 MR. SMITH: Objection.</p> <p>5 A Well, I don't agree with the 6 characterization that there's a heads up phone call 7 file, but of course, it would have been in the 8 natural course of business that we would have kept 9 track of memos related to the content of 10 conversations we had with the FDA. That would have 11 been standard procedure, absolutely.</p> <p>12 Q There was an FDA call file, correct?</p> <p>13 A I don't know if that's what they called 14 it, but any communication with the FDA we absolutely 15 should be keeping that as a record.</p> <p>16 Q Did you review the Johnson and Johnson 17 call file in preparation for today's deposition?</p> <p>18 A I have numerous memos from Johnson and 19 Johnson related to calls with FDA. I don't know 20 that they specifically came out of this file you are 21 calling the call file, but, yes, I have memos.</p> <p>22 Q Ma'am, that's not my question. Did you 23 review the Johnson and Johnson call file in 24 preparation for today's deposition?</p> <p>25 A I have not seen a file characterized as</p>	<p>1 for FDA communications to us, Johnson and Johnson 2 communications to FDA, and they would have included 3 documents related to the phone calls.</p> <p>4 Q What you are you saying is all the paper 5 was destroyed?</p> <p>6 MR. SMITH: Objection.</p> <p>7 A I don't know how our the records are kept.</p> <p>8 Q You said it is only digital, so what 9 happened to the FDA paper call file?</p> <p>10 MR. SMITH: Objection.</p> <p>11 A I don't know what our retention procedures 12 are, so I can't speak to that.</p> <p>13 Q You understand you didn't have the right 14 or authority to destroy any paper, because you were 15 already sued in talc cases in 1984. You knew that, 16 right?</p> <p>17 MR. SMITH: Objection.</p> <p>18 A I don't know about suits in 1984 and I 19 don't know about our retention policy related to 20 talc, so I really can't speak to that.</p> <p>21 Q Let me ask you the question again. In 22 preparation for today's deposition, you never were 23 provided access, nor did you review, the FDA call 24 file, true?</p> <p>25 MR. SMITH: Objection.</p>

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<p style="text-align: center;">Page 50</p> <p>1 A Our documents are in digital form. We no 2 longer have physical folders, physical files that 3 you are referring to. So I reviewed documents that 4 were pulled out of our digital files based on a 5 search related to the communications with the FDA 6 and I do have memos and documents related to those 7 communications that I have reviewed.</p> <p>8 There's not a physical form of a file 9 that you are referring to, so I wouldn't have had it 10 in my hands. So your characterization doesn't match 11 up with the way we currently maintain the records.</p> <p>12 Q What was my question?</p> <p>13 A Your question was about the FDA call file.</p> <p>14 Q What was my question?</p> <p>15 A You can read the question again.</p> <p>16 Q Do you have any idea what my question was?</p> <p>17 MR. SMITH: Objection.</p> <p>18 A I have answered your question.</p> <p>19 Q What was it, if you know you answered the 20 question?</p> <p>21 MR. SMITH: Objection.</p> <p>22 A Did I review documents from the FDA call file.</p> <p>23 Q That wasn't the question. Look at January 24 4, 1984. Did you review this document in</p>	<p style="text-align: center;">Page 52</p> <p>1 I -- I don't recall.</p> <p>2 Q Is this memo in any of the documents you 3 brought with you today?</p> <p>4 A No. We brought the substantive documents 5 of the content of exchanges between Johnson and 6 Johnson and the FDA.</p> <p>7 Q Okay.</p> <p>8 A This is not a substantive document.</p> <p>9 Q What this document says is, "In 1984 at 10 9:10 a.m. I received a telephone call from John 11 Weidinger, Deputy Director, Cosmetic Technology 12 Division of FDA. Mr. Weidinger informed me that FDA 13 had received a citizen petition from a Philip 14 Durelay of Stony Brook, New York requesting a warning 15 statement against asbestos contamination in baby 16 powder. John called to request an a copy of an 17 article referenced in the petition."</p> <p>18 Do you see that?</p> <p>19 A Yes.</p> <p>20 Q Am I correct that Johnson and Johnson 21 knew, and was aware, that when need be, it could 22 bypass FDA staff and go directly to the FDA 23 commissioner if it wanted to.</p> <p>24 MR. SMITH: Objection.</p> <p>25 A So there's a process to escalate to the</p>
<p style="text-align: center;">Page 51</p> <p>1 preparation for today's deposition?</p> <p>2 MR. SMITH: Objection.</p> <p>3 A I don't recall seeing this specific document.</p> <p>4 Q Although this came from the FDA call file and related directly to the issue of asbestos in talc, this was not provided to you, fair?</p> <p>5 MR. SMITH: Objection.</p> <p>6 A I don't recall seeing this specific memo, but I have many other memos that I reviewed.</p> <p>7 Q Ma'am, I'm not the asking you about other memos. We will do that later. I'm saying in preparation for today's deposition, you were never provided with this memo from the FDA call file related to asbestos talc testing, correct?</p> <p>8 A I don't recall seeing this specific memo.</p> <p>9 Q So the answer to my question is you were never provided it, correct?</p> <p>10 MR. SMITH: Objection.</p> <p>11 A So the answer to your question is I don't recall seeing this specific memo.</p> <p>12 Q So you did get it, you just don't remember?</p> <p>13 MR. SMITH: Objection.</p> <p>14 A If I don't remember, how can I tell you if</p>	<p style="text-align: center;">Page 53</p> <p>1 commissioner if there's an issue of sufficient import and merit.</p> <p>2 Q And when it came to Johnson's Baby Powder, Johnson and Johnson had both the power and the access to bypass FDA staff and go directly to the FDA commissioner, if it wanted to, correct?</p> <p>3 MR. SMITH: Objection.</p> <p>4 A As I said, for topics of significant import, absolutely we could escalate to the commissioner as needed.</p> <p>5 Q No citizen or doctor had that kind of access, correct?</p> <p>6 MR. SMITH: Objection.</p> <p>7 A I believe the citizens' petition process is the mechanism by which citizens can approach the FDA when they have certain concerns apropos the memo you showed me.</p> <p>8 Q So you think an average citizen can just bypass the FDA staff and go right to the commissioner when it has issue? That's what you believe?</p> <p>9 MR. SMITH: Objection.</p> <p>10 Q Just like Johnson and Johnson can?</p> <p>11 MR. SMITH: Objection.</p> <p>12 A We don't bypass. We escalate, meaning if</p>

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<p>1 there's an issue that's been discussed with the FDA 2 staff members as appropriate to preview a topic and 3 there's some issue that arises that needs a higher 4 level of interaction, those issues can be escalated, 5 but we do not bypass the communication process. 6 MR. SMITH: While there is no 7 question pending, can we have a bathroom break? 8 THE VIDEOGRAPHER: The time is 9 approximately 11:03 a.m and we are going off the 10 record.</p> <p>11 (Recess taken) 12 (Notebooks are marked P-3, 4 and 5.)</p> <p>13</p> <p>14 THE VIDEOGRAPHER: We are back on the 15 record. The time is approximately 11:14 a.m.</p> <p>16</p> <p>17 BY MR. PLACITELLA:</p> <p>18</p> <p>19 Q Dr. Nicholson, before we broke you talked 20 about the ability to escalate an issue to the 21 commissioner. What was the process for doing that?</p> <p>22 A I don't know the exact process.</p> <p>23 Q What kind of issues got escalated to the 24 commissioner?</p> <p>25 MR. SMITH: Objection.</p>	<p>1 A I don't know. 2 Q Now, when Johnson and Johnson feels like 3 it is suffering from adverse public relations 4 concerning the safety of its products, is that the 5 type of thing they escalate to the commissioner of 6 the FDA?</p> <p>7 MR. SMITH: Objection.</p> <p>8 A No. Public relations has nothing to do 9 with FDA interactions and what things would 10 escalate.</p> <p>11 Q Well, you did understand and consider 12 escalating the issues related to the safety of baby 13 powder and asbestos to the commissioner, correct?</p> <p>14 MR. SMITH: Objection.</p> <p>15 A Not the safety of asbestos and baby 16 powder. The issue was testing of asbestos in baby 17 powder, and the fact that there was incorrect 18 testing results and people were making significant 19 decisions based on incorrect testing methods.</p> <p>20 Q And it was Johnson and Johnson's position 21 that they needed to go directly to the commissioner 22 and voice their position, correct?</p> <p>23 MR. SMITH: Objection.</p> <p>24 A No. That's not correct.</p> <p>25 Q I'm not correct? What is correct?</p>
Page 55	Page 57
<p>1 Q By Johnson and Johnson. 2 A I think escalations were extremely rare. 3 If there's a discussion about a specific topic at a 4 certainly level of management, whether it be with 5 the director of the cosmetic division, then that 6 could be escalated to the commissioner.</p> <p>7 Q Does the ordinary citizen have the ability 8 to do that?</p> <p>9 A An ordinary citizen would use the citizen 10 petition process to interact with the FDA.</p> <p>11 Q So the ordinary citizen has no ability to 12 get directly to the FDA commissioner like Johnson 13 and Johnson does, correct?</p> <p>14 A I don't know if they can or cannot reach 15 the commissioner.</p> <p>16 Q What about medical doctors who are 17 concerned about the safety and health of their 18 patients? Do they have direct access to the 19 commissioner?</p> <p>20 MR. SMITH: Objection.</p> <p>21 A I don't know.</p> <p>22 Q What about members of Congress, can they 23 just call up the commissioner and demand access to 24 the commissioner?</p> <p>25 MR. SMITH: Objection.</p>	<p>1 MR. SMITH: Objection.</p> <p>2 A Johnson and Johnson deals directly with 3 the individuals responsible for the oversight of 4 cosmetics. If there's some issue that needs to be 5 escalated based on various considerations of the 6 importance and impact, that could be escalated to 7 the commissioner.</p> <p>8 Q Well, Johnson and Johnson took the 9 position that it had access to the commissioner on 10 the issue of whether asbestos was in baby powder, 11 correct?</p> <p>12 A Incorrect.</p> <p>13 Q 476 is an addendum to memorandum from 14 March 23, 1972. Have you seen this before?</p> <p>15 A I need one minute to look at it.</p> <p>16 Q Sure.</p> <p>17 A I have seen communications related to this 18 topic. I don't know if I've seen this exact 19 addendum. Without seeing the rest of the documents, 20 it is hard to tell.</p> <p>21 Q It is not part of the information you 22 reviewed in preparation for today's deposition?</p> <p>23 MR. SMITH: Objection.</p> <p>24 A I didn't say that. I reviewed -- if I 25 reviewed it, I reviewed the whole letter. You only</p>

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<p>1 gave me a page.</p> <p>2 Q Do you have the whole letter, because I 3 don't have it?</p> <p>4 A I may. If you would like, I'll take time 5 to look through.</p> <p>6 Q Let's make a note of things we want to 7 look at during the break.</p> <p>8 Do you see here it talks about a call 9 with the Deputy Director, Bureau of Foods? Do you 10 see that?</p> <p>11 A Yes.</p> <p>12 Q About Johnson's Baby Powder.</p> <p>13 A I see that.</p> <p>14 Q Do you see it says, "I reviewed further 15 with Mr. Bernard the advisability of Johnson and 16 Johnson going to the commissioner to inform him of 17 our data regarding our baby powder being free of 18 asbestos so that he will be prepared to allay the 19 panic of the mothers which may result from the 20 consumer initiated publicity."</p> <p>21 A Yes.</p> <p>22 Q Do you see that?</p> <p>23 A Yes.</p> <p>24 Q Did that ever happen?</p> <p>25 A That they discussed with the commissioner.</p>	<p>1 Q When the FDA made a decision how they were 2 going to respond to citizens raising questions about 3 the safety of baby powder, they actually went to 4 Johnson and Johnson and said, can you give us the 5 research to support our decision, correct?</p> <p>6 MR. SMITH: Objection.</p> <p>7 Q Even after they made the decision, 8 correct?</p> <p>9 MR. SMITH: Objection.</p> <p>10 A I'm sorry, I'm confused by your question.</p> <p>11 Q When the FDA was responding to concerns 12 that were raised by citizens about the safety of 13 baby powder, it actually went to Johnson and Johnson 14 and said, this is what we decided, but we need you to 15 give us the backup for our analysis. That's what 16 happened, right?</p> <p>17 MR. SMITH: Objection.</p> <p>18 Q That's how intimate the connection was 19 between the two of you.</p> <p>20 MR. SMITH: Objection.</p> <p>21 Q Correct?</p> <p>22 A No. I disagree with your 23 characterization.</p> <p>24 Q 497 is correspondence from Craig Bernard 25 dated November 3, 2008, subject, meeting with J and</p>
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<p>1 I believe there was a discussion with the 2 commissioner.</p> <p>3 Q Now when the FDA is responding to citizens 4 concerns about the safety of baby powder, it, in 5 fact, relied upon Johnson and Johnson for research 6 and support in order to respond to those concerns. 7 Is that true?</p> <p>8 MR. SMITH: Objection.</p> <p>9 A In 1972, there was a lot of work being 10 done around asbestos testing and incorrect test 11 results coming out. Johnson and Johnson's Baby 12 Powder is free of asbestos. So there were some 13 concerns about incorrect information being 14 attributable to our products.</p> <p>15 Q That wasn't my question. My question was 16 when the FDA is responding to citizens concerns 17 about the safety of Johnson's Baby Powder, it 18 actually relied upon Johnson and Johnson to help 19 write and respond to the citizens concerns, correct?</p> <p>20 MR. SMITH: Objection.</p> <p>21 A I'm not sure I agree with that 22 characterization, but I'll say that Johnson and 23 Johnson was very involved in the technologic 24 methodological development of asbestos testing because 25 we had significant expertise in this area.</p>	<p>1 J. Do you see that?</p> <p>2 A Yes, I do.</p> <p>3 Q It states, "Hi, Mark. You recall a couple 4 of months ago we met with Bill Casalarus' office 5 and spoke about the citizens petition with the FDA 6 that is requesting to have warning labels placed on 7 products containment. Here is an update on that 8 activity. Kathy Willie," do you know who Kathy 9 Willie is?</p> <p>10 A She's a former Johnson and Johnson 11 employee.</p> <p>12 Q What was her job?</p> <p>13 A I don't recall her exact title.</p> <p>14 A "Kathy Willie at Johnson and Johnson 15 informed me that at a recent science meeting in 16 Washington, D.C. she had a side conversation with a 17 key figure from the FDA cosmetic group that is 18 responsible for responding to the citizens 19 petition."</p> <p>20 Do you know anything about a side 21 conversation?</p> <p>22 A I'm reading this here.</p> <p>23 MR. SMITH: Objection.</p> <p>24 A I'm looking at this here. This is an 25 Imerys document.</p>

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<p>1 Q Do you know anything about the side 2 conversation that you, Johnson and Johnson, had with 3 the FDA official in 2008 referenced here? 4 MR. SMITH: Objection. 5 A This is the only reference I've seen to 6 that conversation. I'll point out, again, this is 7 an Imerys document. 8 Q But it is their business record about a 9 meeting it had with you, Johnson and Johnson. 10 Right? 11 MR. SMITH: Objection. 12 A It is an e-mail from one person to another 13 with an Imerys referring to some conversation that 14 was had, that's correct. 15 Q With Johnson and Johnson? 16 A Correct. 17 Q He indicated the "FDA would rule against 18 the petition and would not require a warning label 19 on cosmetic products, but the FDA is looking for 20 scientific support from industry that will help 21 justify their position." Do you know anything about 22 that? 23 A I don't know about this side conversation, 24 but I'm reading down further and I know what they 25 are referring to with regard to development of a review</p>	<p>1 done and that was a review of the scientific 2 literature related to a specific safety concern, 3 which was prepared and available to the FDA. 4 Q Ma'am, what I'm asking you is do you know 5 anything about these side conversations that Johnson 6 and Johnson executives were having with people at 7 the FDA asking for support for denying citizen 8 petitions. That's all I'm asking. 9 Do you know anything, since you are 10 here on behalf of Johnson and Johnson and the 11 communications it had with the FDA. Do you know 12 anything about those side conversations? 13 MR. SMITH: Objection. This witness 14 is here about communications. 15 MR. PLACITELLA: Please don't do 16 this. 17 MR. SMITH: Regarding testing for 18 asbestos. That's why she is here. 19 Q Do you know anything about the side 20 conversation, Ma'am? 21 A I only know what's written here in this 22 Imerys document. I have not seen this before and it 23 is not related to asbestos testing. 24 Q It says on the bottom, I'll highlight it 25 for you.</p>
<p>1 article related to talc safety. 2 Q But you don't know anything about the side 3 conversation with the FDA asking Johnson and Johnson 4 for support in order to deny the citizen's petition. 5 Do you know about that side conversation? 6 MR. SMITH: Objection. 7 A I'm reading this along with you and 8 I see the FDA had already made their decision about 9 the petition and they were looking for some 10 scientific support, and supposedly that was part of 11 this conversation that you are pointing out in this 12 memo that is an Imerys memo. 13 Q That's exactly my point. So even after 14 the FDA had made its decision, it went to Johnson 15 and Johnson and said, can you give us some support 16 for we are about to say. That's what happened, 17 according to this memo. 18 MR. SMITH: Objection. 19 Q Right? 20 A I believe in your question you are 21 implying they had scientific support, but they were 22 going to rule against it. I think that's an 23 incorrect characterization. 24 I'm well aware of the Muscat and 25 Huncharek epidemiologic review of talc safety that was</p>	<p>1 "We also know the FDA is looking to 2 include in their comments that talc does not contain 3 asbestos, and thus talc use would not cause a 4 concern from this risk perspective. We know this 5 because FDA asked Personal Care Products Council for 6 their updated specifications for talc, which the 7 council in turn asked J and J and RTM for assistance 8 with." Do you see that? 9 A Yes. 10 Q So this document does talk about asbestos 11 testing and information available from 12 Johnson and Johnson, correct? 13 MR. SMITH: Objection. 14 A That's not correct. It says that the talc 15 does and they are making reference to the industry 16 specification they are getting, not from Johnson and 17 Johnson, but the Personal Care and Product Council. 18 Q Who went to Johnson and Johnson and asked 19 for help, correct? 20 MR. SMITH: Objection. 21 A I can't follow who went to what for whom. 22 There are probably four different people mentioned 23 in that sentence. 24 A Says counsel in turn asked Johnson and 25 Johnson for assistance. Is it that hard to read?</p>
	<p>Brody Deposition Services</p>

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<p>1 MR. SMITH: Objection.</p> <p>2 A I hear your question. They are referring 3 to the J41 specification for cosmetic talc that you 4 get off of internet, so I don't see they would need 5 J and J's assistance to Google it and print it out.</p> <p>6 Q Ma'am, did I ask you anything about Google 7 or J41?</p> <p>8 A You did.</p> <p>9 Q I didn't.</p> <p>10 A You asked about this updated specification 11 for talc.</p> <p>12 Q Ma'am, all I asked you was, does this memo, 13 in fact, reference asbestos testing and the issue of 14 asbestos in talc. That was my question.</p> <p>15 A This memo specifically said talc, not 16 containing asbestos in the current product 17 specifications, which would go to the fact that this 18 is talc not containing asbestos.</p> <p>19 I'm well aware of this time period 20 and the topic at hand, and it is not about asbestos 21 testing.</p> <p>22 Q Let me read it for the record and then 23 I'll move on. "We also know the FDA is looking 24 to include in their comments that talc does not 25 contain asbestos, and thus talc use would not cause</p>	<p>1 A That is correct. In the late '60s and 2 early '70s, people were talking about the health 3 effects of tremolite and those issues were dealt 4 with with preclinical animal testing.</p> <p>5 Q I didn't ask you about animal testing. 6 I'm asking you a very specific question. Am I 7 correct that as far back as 1969, Johnson and 8 Johnson's medical director had concerns about the 9 health effects related to tremolite, that's my 10 question.</p> <p>11 MR. SMITH: Objection.</p> <p>12 Q Not what you did in response. I'll ask 13 that as a separate question. Do you understand 14 that?</p> <p>15 MR. SMITH: Objection.</p> <p>16 A I understand your question. The way you 17 are phrasing it is misleading, and it implies that 18 for many years starting in 1969, people were 19 concerned about tremolite, and that's incorrect. 20 It was a very small period of time people were 21 concerned and that scientific question was dealt 22 with in the early '70s with preclinical animal 23 testing.</p> <p>24 Q And it was totally resolved from Johnson 25 and Johnson's perspective in the early '70s, the</p>
<p>1 a concern from this risk perspective." That's what 2 it says, correct?</p> <p>3 A That's what it says, yes.</p> <p>4 Q I want to talk a minute about potential 5 hazards related to talc that were known and 6 discussed inside Johnson and Johnson relevant to 7 whether talc was misbranded under FDA regulations. 8 Okay? Are you with me?</p> <p>9 A Yes.</p> <p>10 Q Am I correct, and can we agree, that 11 Johnson and Johnson was concerned about the medical 12 effect of tremolite for decades prior to the 2008 13 petitions?</p> <p>14 MR. SMITH: Objection.</p> <p>15 A Not for the decades prior to 2008.</p> <p>16 Q Can we agree that as far back as 1969 the 17 Johnson and Johnson medical director expressed 18 concern about the medical effects of tremolite?</p> <p>19 MR. SMITH:</p> <p>20 A In the late '60s and early '70s there were 21 questions about tremolite and that was dealt with 22 with some preclinical animal studies.</p> <p>23 Q Am I correct as far back as 1969 the 24 medical director of Johnson and Johnson was 25 concerned about the health effects of tremolite?</p>	<p>1 potential health effects from tremolite. Is that 2 what you are saying?</p> <p>3 MR. SMITH: Objection.</p> <p>4 A Yes.</p> <p>5 Q Can we agree that Johnson and Johnson's 6 Baby Powder products contained tremolite and 7 actinolite that were classified as fiber by federal 8 regulations?</p> <p>9 MR. SMITH: Objection.</p> <p>10 A That is a compound question that you are 11 asking. Tremolite and actinolite are not asbestos.</p> <p>12 Q Ma'am, that's not my question. My 13 question is can we agree that talc baby products 14 that contained tremolite and actinolite were 15 classifiable as fiber under federal regulations?</p> <p>16 MR. SMITH: Objection.</p> <p>17 A You have to show me the regulations you 18 are referring to.</p> <p>19 Q J44 is an April 26, 1973 memo to Mr. 20 Johnston on Johnson and Johnson letterhead, 21 correct?</p> <p>22 A Yes.</p> <p>23 Q This was after the time you say Johnson 24 and Johnson hadn't resolved the issue of whether 25 there was a danger related to tremolite, correct?</p>

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<p>1 MR. SMITH: Objection.</p> <p>2 A That's correct, in preclinical animal 3 testing.</p> <p>4 Q You are familiar with this document?</p> <p>5 A I've seen this document, yes.</p> <p>6 Q In this document it talks about a visit to 7 the mine by Mr. Ashton and Mr. Miller and Mr. 8 Zeitz, correct?</p> <p>9 A Yes.</p> <p>10 Q And it says, "It is our joint conclusion 11 that we should not rely on the clean mine approach 12 as a protective device for baby powder in the 13 current asbestos or asbestiform controversy. We 14 believe this mine to be very clean, however, we are 15 also confident that fiber forming or fiber type 16 materials could be found. Usefulness of the clean 17 mine approach for asbestos only is over." Do you 18 see that?</p> <p>19 A Yes.</p> <p>20 Q When you go to the second page, the reason 21 I'm asking you this because it is about the FDA. It 22 says, "if the FDA Food Division, which is moving 23 more rapidly than the cosmetic division, publishes a 24 standard, it will be probably to ban an asbestiform 25 or fibrous material in talc. That could eliminate</p>	<p>1 non-asbestiform tremolite, as of at least 1974, could 2 be ground up and satisfy the definition of 3 asbestiform tremolite, correct?</p> <p>4 MR. SMITH: Objection.</p> <p>5 A I don't recall that specific statement, 6 but I'll restate anything before 1976 with the J41 7 standard is likely to be confused and incorrect with 8 regard to the characterization of asbestos.</p> <p>9 Q We are going to get to that, I promise 10 you.</p> <p>11 364 is a memo from the FDA dated May 12 14, 1974. You have seen this, correct?</p> <p>13 A I need one minute to look at it, please. 14 Go ahead.</p> <p>15 Q In this memo, the FDA states, "Tremolite 16 is the commonest asbestos mineral found as a 17 contaminant of talc. It occurs in asbestiform and 18 non-asbestiform varieties. This sample is a chunky 19 tremolite, not the asbestiform variety. But when it 20 is ground, it produces some thin, straight particles 21 which conform to the definition of fibers in the 22 method which our distinguishable produced by 23 asbestiform tremolite on grinding."</p> <p>24 That is something that Johnson and 25 Johnson understood as of this time, correct?</p>
<p>1 the current uses of talc in packaging materials. 2 These talc contained wildly varying amounts of 3 tremolite or fibrous talc. Our Baby Powder contains 4 talc fragments classifiable as fiber. Occasionally 5 subtrace quantities of tremolite or actinolite are 6 identifiable on the microscope and these might be 7 classified as asbestos fibers." Did I read that 8 correctly?</p> <p>9 A You did.</p> <p>10 Q Now, you understand that it was, and can 11 we agree that the FDA's position was that "non 12 asbestiform tremolite could be ground up so that it 13 conformed to the definition of fiber requiring 14 regulation and that it would be as indistinguishable 15 from asbestos tremolite." You, Johnson and Johnson, 16 knew that, correct?</p> <p>17 MR. SMITH: Objection.</p> <p>18 A You are showing me documents from the 19 early '70s, so I need to know what documents you are 20 referring to because whatever was done before 1976 21 is during methods developments, so any definitive 22 statements during that time around the 23 characterization of asbestos are probably incorrect.</p> <p>24 Q Ma'am, that's not my question, please. My 25 question is, it was the position of the FDA that</p>	<p>1 MR. SMITH: Objection.</p> <p>2 A That is correct. This in the context of 3 developing methods. They are not saying tremolite 4 is asbestos. They are trying to figure out what is 5 the right method to use to distinguish between other 6 particles and the type of asbestos that could be 7 harmful.</p> <p>8 Q Ma'am, I know you have a story to tell and 9 you can do it when your lawyer asks you questions. 10 But I would ask you, please, to just answer my 11 question.</p> <p>12 My question was not -- didn't ask for 13 a long explanation. You understand that, right?</p> <p>14 MR. SMITH: Let me state for the 15 record, Dr. Nicholson, just ignore those insulting 16 comments. Just ignore them. Okay. You are here. 17 Listen to the question, answer it.</p> <p>18 The gratuitous comments we can't 19 stop. I'm told this is how he behaves at a 20 deposition, but just ignore it, okay?</p> <p>21 A Yes. Could you restate your question, 22 please?</p> <p>23 Q Sure. In this memo, the FDA is stating a 24 position concerning tremolite. That's all I'm 25 asking you, correct?</p>

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<p>1 A That's incorrect. In this memo the FDA is 2 talking about methods to distinguish asbestos, real 3 asbestos using different microscopic techniques. 4 This is not a declaration of a position, it is a 5 discussion of methods.</p> <p>6 Q Can you show me, Ma'am, in any of the 7 materials you brought with you today where the FDA 8 changed its position concerning non-asbestiform 9 tremolite being -- and if you can tag that, we will 10 do that after lunch can you do that?</p> <p>11 MR. SMITH: Objection to the form.</p> <p>12 Q Let me ask you this question. Am I 13 correct, and can we agree that five to eight percent 14 of the Johnson and Johnson talc, talc sold by 15 Johnson and Johnson, contained particles that are 16 capable of damaging the lungs of human beings?</p> <p>17 MR. SMITH: Objection.</p> <p>18 A No.</p> <p>19 Q 467 is an August 13, 1971 memo on Johnson 20 and Johnson letterhead, the subject being talc. I'm 21 going to refer you to Section G. It states, "It is 22 generally accepted that the lung damaging particles 23 of minerals are below ten microns. Roughly we have 24 about five to eight percent of such in our talc." 25 Did I read that correctly?</p>	<p>1 A Let me review the document. There are 2 multiple points in here, not necessarily related. 3 Okay. Go ahead. Your question, 4 please. Please ask the question again.</p> <p>5 Q This particular document talks about talc 6 that was being mined and sold by Johnson and 7 Johnson, correct?</p> <p>8 A That is correct, from Windsor Minerals, 9 which contain industrial talc as well as cosmetic 10 talc, and it is very difficult to see what they are 11 referring to in different points. There's a 12 mixture.</p> <p>13 Q You understand that both the industrial 14 talc and the cosmetic talc sold by Johnson and 15 Johnson came out of the exact same Hammondsburg 16 mine. You know that, correct?</p> <p>17 A That is not correct. There were different 18 mines, mine shafts and geographic locations for 19 cosmetic versus industrial talc.</p> <p>20 Q That wasn't my question. Do you 21 understand, Ma'am, that the cosmetic and industrial 22 talc sold by Johnson and Johnson came out of the 23 Hammondsburg mine, correct?</p> <p>24 MR. SMITH: Objection.</p> <p>25 Q You know that?</p>
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<p>1 A You did read that correctly, but we don't 2 know this refers to cosmetic talc. We have to go 3 back and review the beginning of the document. 4 Absolutely incorrect for our cosmetic talc and has 5 always been true.</p> <p>6 Q So it has been true for your industrial 7 talc, but not your cosmetic talc. Is that what you 8 are saying?</p> <p>9 A What I'm saying is I'll need to go back 10 and look because cosmetic talc does not contain 11 particles.</p> <p>12 Q Okay. Go back and look. Let me help you. 13 Look at Section C. It says the, Bureau of Mines 14 expert who testified at the behest of the FDA 15 commented on the poor grade talc in our Windsor 16 Mine, but mentioned the ore next to the outlying 17 rock contained asbestos. It is imperative that 18 careful selection of the ore be maintained at the 19 mines. It is always possible that the FDA may 20 inspect the mines and our records." Do you see 21 that?</p> <p>22 A Yes.</p> <p>23 Q What they are talking about, and when you 24 look at B, they are talking about the Shower to 25 Shower and your medicated product, correct?</p>	<p>1 A That wasn't your question before. You 2 said the exact same mine. They come from different 3 mine shafts, different quality of talc, just to be 4 clear.</p> <p>5 Q Can we agree, Ma'am, that the cosmetic 6 talc and industrial talc that was sold by Johnson 7 and Johnson came out of the Hammondsburg mine owned 8 by Johnson and Johnson?</p> <p>9 MR. SMITH: Objection.</p> <p>10 A I don't know the names of all the mines. 11 I don't believe Hammondsburg was the only source of 12 talc, so I can't answer that specifically. But I 13 know that cosmetic talc did not come from the 14 same geologic formations.</p> <p>15 Q How do you know that?</p> <p>16 A I've read many documents, spoken to many 17 experts in the field including John Hopkins and 18 other consultants that we have. They are expert 19 geologists.</p> <p>20 Q So let's just be clear where we are. Are 21 you saying that the cosmetic talc and the industrial 22 talc sold by Johnson and Johnson did not come from 23 the Hammondsburg mine?</p> <p>24 MR. SMITH: Objection.</p> <p>25 A I didn't say that.</p>

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<p>1 Q So my question was, according to Johnson 2 and Johnson, it is generally accepted that lung 3 damaging particles of minerals are below ten microns 4 and that according to Johnson and Johnson, you had 5 about five to eight percent of such minerals in your 6 talc as of 1971, correct?</p> <p>7 MR. SMITH: Objection.</p> <p>8 A I'm reading the statement here as you are. 9 That's what it says.</p> <p>10 Q Now, am I correct that the talc in Johnson 11 and Johnson products is capable of reaching, when 12 inhaled, is capable of reaching deep into the human 13 organs?</p> <p>14 MR. SMITH: Objection.</p> <p>15 A I'm not an inhalation toxicology expert.</p> <p>16 Q Do you agree with me that inhaled talc 17 could reach deep into the lungs?</p> <p>18 MR. SMITH: Objection.</p> <p>19 A I'm not an inhalation toxicology expert.</p> <p>20 Q You don't know that? You, Johnson and 21 Johnson, don't know that?</p> <p>22 MR. SMITH: Objection.</p> <p>23 A I'm not -- I personally am not an 24 inhalation toxicology expert, so I can't comment on 25 that.</p>	<p>1 lawyer. I'm asking you to answer my question. 2 As you sit here today you no evidence 3 that Johnson and Johnson ever revealed to the FDA 4 that it was of the opinion that inhaled talc could 5 reach deep into the lungs, correct?</p> <p>6 MR. SMITH: Objection.</p> <p>7 A I have not reviewed the inhalation 8 communications between the FDA and Johnson and 9 Johnson.</p> <p>10 Q Now, am I correct, or can we agree that 11 Johnson and Johnson internally acknowledged that 12 very low levels of chrysotile asbestos found as a 13 contaminant in talc pose a severe health hazard?</p> <p>14 MR. SMITH: Objection. Can you read 15 that question back.</p> <p>16 (The above question is read.)</p> <p>17 MR. SMITH: Note my objection.</p> <p>18 A I didn't understand the question.</p> <p>19 Q Can we agree internally at Johnson and 20 Johnson that you acknowledged that very low levels 21 of exposure to chrysotile asbestos found as a 22 contaminant in talc, pose a severe health hazard?</p> <p>23 MR. SMITH: Objection.</p> <p>24 A No.</p> <p>25 Q 69 is the Johnson and Johnson Baby Powder</p>
Page 79	Page 81
<p>1 Q Do you know whether Johnson and Johnson 2 ever related to the FDA that inhaling its talc could 3 reach deep into the lungs?</p> <p>4 MR. SMITH: Objection.</p> <p>5 A Since I'm not an expert in that area, I 6 would not recall specifics of that information.</p> <p>7 Q So as you sit here today, you, Johnson and 8 Johnson, don't know whether you ever told the FDA 9 that inhaled talc could reach deep into the lungs?</p> <p>10 MR. SMITH: Objection.</p> <p>11 A I'm not an inhalation toxicology expert. 12 I can't comment on that.</p> <p>13 Q I'm not asking whether you are an expert. 14 I'm asking about what information Johnson and 15 Johnson had that was related to the FDA.</p> <p>16 As you sit here today, you, Johnson 17 and Johnson, have no evidence that you ever told the 18 FDA that inhaled talc could reach deep into the 19 lungs, correct?</p> <p>20 MR. SMITH: Objection.</p> <p>21 A My scope for today was information about 22 asbestos testing communications between the FDA and 23 Johnson and Johnson. Your question is outside of 24 the scope.</p> <p>25 Q With all due respect, you are not a</p>	<p>1 fact book, July 1974. I'm going to refer you -- who 2 is Vernon Zeitz? Do you know?</p> <p>3 A I don't know Vernon Zeitz.</p> <p>4 Q And I'm going to refer you to page 5, 5 under summary and remarks. It states, "The use of 6 citric acid in the depression of chrysotile asbestos 7 and other mineral species has been developed at 8 Windsor Minerals in response to the potential need 9 for means to exclude extremely local levels of these 10 contaminants from the finished product of the 11 benefaction process. The use of these systems is 12 strongly urged by the writer to provide the 13 protection against what are currently considered to 14 be materials presenting a severe health hazard and 15 are potentially present in all talc ores in use at 16 this time." Did I read that correctly?</p> <p>17 A You did.</p> <p>18 Q Did you ever see this before?</p> <p>19 A I haven't. This document is called a 20 floatation method and so it would take some review 21 and discussion with an expert to really understand 22 what this is about, what it is referring to.</p> <p>23 Q So you never saw this document at any time 24 in preparation for testimony you have given 25 anywhere?</p>

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<p>1 MR. SMITH: Objection.</p> <p>2 A I don't recall seeing it before. I may 3 have, but I certainly did not review it in detail 4 for today.</p> <p>5 Q Can we agree that Johnson and Johnson 6 those and acknowledges that talc containing 7 asbestos fibers is a known human carcinogen?</p> <p>8 MR. SMITH: Objection.</p> <p>9 A Can you read that again? There was a bit 10 confusing to me.</p> <p>11 Q Yes. Can we agree that you, Johnson and 12 Johnson, acknowledge that talc containing 13 asbestos fibers is a known human carcinogen?</p> <p>14 MR. SMITH: Objection.</p> <p>15 A We know that asbestos is a carcinogen, if 16 that's your question.</p> <p>17 Q My question is, talc containing 18 asbestos fibers is a known human carcinogen. 19 That's something you know at Johnson and Johnson, 20 correct?</p> <p>21 MR. SMITH: Objection.</p> <p>22 A That is correct, that asbestos is a 23 carcinogen. If it were any of our products, it 24 would still be a carcinogen.</p> <p>25 Q Now, Johnson and Johnson, can we agree</p>	<p>1 Can you clarify?</p> <p>2 Q Sure. Let me ask you. Maybe that was a 3 bad question.</p> <p>4 Can we agree that were reports in the 5 scientific literature indicating that talc 6 contaminated with asbestos is a cause of 7 mesothelioma in women?</p> <p>8 MR. SMITH: Objection.</p> <p>9 A I'm not aware of that literature.</p> <p>10 Q Am I correct that, and can we agree, that 11 Johnson and Johnson internally has acknowledged that 12 because tremolite and anthophyllite are known 13 contaminants of talc, date suggests that rare cases 14 of mesothelioma among women with no other 15 identifiable exposure might be related to exposure 16 to cosmetic talc?</p> <p>17 MR. SMITH: Objection.</p> <p>18 A No.</p> <p>19 Q 216 is a memo from 1977 entitled 20 Mesothelioma Talc Medical Research. Do you see 21 that?</p> <p>22 A Yes.</p> <p>23 Q With Johnson and Johnson Bates number on 24 it. Do you see that?</p> <p>25 A Yes.</p>
<p>1 that Johnson and Johnson knows and acknowledges 2 people can development the disease mesothelioma from 3 non occupational exposure to asbestos?</p> <p>4 MR. SMITH: Objection.</p> <p>5 A Yes.</p> <p>6 Q Can we agree that studies that Johnson and 7 Johnson were aware of demonstrate that both talc and 8 asbestos have been found in women who are non 9 occupationally exposed to asbestos?</p> <p>10 MR. SMITH: Objection.</p> <p>11 A Yes.</p> <p>12 Q Can we agree that tremolite and 13 anthophyllite are known contaminants of talc?</p> <p>14 MR. SMITH: Objection.</p> <p>15 A They can be. They are not asbestos.</p> <p>16 Q Can we agree that talc, contaminated talc, 17 has been implicated as a cause of mesothelioma in 18 women?</p> <p>19 MR. SMITH: Objection.</p> <p>20 A Contaminated talc. You have to be more 21 specific.</p> <p>22 Q Talc contaminated with asbestos has been 23 implicated as a cause of mesothelioma in women.</p> <p>24 MR. SMITH: Objection.</p> <p>25 A What do you mean by implicated, please?</p>	<p>1 Q If we go to the section of the memo on 2 talc, it states, "However, in several mesothelioma 3 patients studied both talc fibers and tremolite were 4 detected. In fact, the majority of asbestos bodies 5 isolated from the lungs of women in the general 6 population have tremolite or anthophyllite, and 7 because tremolite and anthophyllite are known 8 contaminants of talc, this data suggests that rare 9 cases of mesothelioma among women with no other 10 identifiable exposure might be related to exposure 11 to cosmetic talc." Did I read that correctly?</p> <p>12 A You read that correctly, but I disagree 13 with that conclusion.</p> <p>14 Q I wasn't asking you what you agree with. 15 I was asking you whether this was information in the 16 possession of Johnson and Johnson.</p> <p>17 A This is information in the possession of 18 Johnson and Johnson, but there are rare cases with 19 no identifiable, might be related. It is not 20 scientific data, it is a hypothesis.</p> <p>21 Q Ma'am, I'm just asking whether the 22 information contained in this Johnson and Johnson 23 document was information known to Johnson and 24 Johnson, at least in 1997. That's all I wanted to 25 know.</p>

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<p>1 MR. SMITH: Objection.</p> <p>2 A It is written down here on this piece of</p> <p>3 paper. That's what I can agree to.</p> <p>4 Q So the answer to my question is yes?</p> <p>5 MR. SMITH: Objection.</p> <p>6 A I say it is written down on this piece of</p> <p>7 paper. This is not a sort of factual acknowledgment</p> <p>8 that this association was something Johnson and</p> <p>9 Johnson thought was scientific, rigorous, robust and</p> <p>10 legitimate.</p> <p>11 Q My question to you was, the information in</p> <p>12 this Johnson and Johnson document was information as</p> <p>13 of 1997 that Johnson and Johnson looked at and</p> <p>14 considered and was part of its business records,</p> <p>15 correct?</p> <p>16 MR. SMITH: Objection.</p> <p>17 A This was written down on a Johnson and</p> <p>18 Johnson document. That, I can degree to.</p> <p>19 Q Can we agree that Johnson and Johnson is</p> <p>20 required to be honest and forthright when dealing</p> <p>21 with government agencies on product safety?</p> <p>22 MR. SMITH: Objection?</p> <p>23 A Yes.</p> <p>24 Q Can we agree that when relating</p> <p>25 information to the FDA on product safety, the whole</p>	<p>1 asbestos in Johnson and Johnson talc products, was a</p> <p>2 question that was repeatedly raised by the FDA</p> <p>3 beginning at least in the early '70s, correct?</p> <p>4 A The way you are saying it implies it was a</p> <p>5 specific question about Johnson and Johnson talc</p> <p>6 powders. It was not. It was about cosmetic talc in</p> <p>7 general.</p> <p>8 Johnson and Johnson was not</p> <p>9 questioning specifically about the integrity of our</p> <p>10 products per se by your question.</p> <p>11 Q So, is your testimony today that Johnson</p> <p>12 and Johnson -- excuse me, that the FDA never raised</p> <p>13 the issue with Johnson and Johnson as to whether</p> <p>14 there was any evidence of asbestos in any Johnson</p> <p>15 and Johnson products?</p> <p>16 A I didn't say that. The FDA asked us in</p> <p>17 the '70s, or we offered in the '70s, information on</p> <p>18 our testing of our products around the issue of</p> <p>19 asbestos.</p> <p>20 Q Did the FDA ask you whether there was any</p> <p>21 evidence of any amount of asbestos in any Johnson</p> <p>22 and Johnson cosmetic talc product?</p> <p>23 A I'm sure there was some question to that</p> <p>24 effect asked.</p> <p>25 Q And the answer by Johnson and Johnson was</p>
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<p>1 truth is required and not just part of the truth.</p> <p>2 Can we have agree to that?</p> <p>3 A The truth related to whatever the issue at</p> <p>4 hand is, yes, I'll agree to that.</p> <p>5 Q And it is considered a crime to</p> <p>6 intentionally mislead a government agency. Do you</p> <p>7 understand that?</p> <p>8 MR. SMITH: Objection.</p> <p>9 A Yes, I do.</p> <p>10 Q Now, am I correct whether there was</p> <p>11 asbestos in the Johnson and Johnson talc products</p> <p>12 was raised repeatedly by the FDA beginning in the</p> <p>13 early '70s?</p> <p>14 A It was raised. I don't know what that</p> <p>15 means.</p> <p>16 Q The issue was -- the question came up over</p> <p>17 and over again beginning in the 1970s and was posed</p> <p>18 to Johnson and Johnson, whether any Johnson and</p> <p>19 Johnson talc product contained asbestos. Can we</p> <p>20 agree with that?</p> <p>21 MR. SMITH: Objection.</p> <p>22 A That's correct, and Johnson and Johnson</p> <p>23 talc never contained asbestos.</p> <p>24 Q We will get to that part. All I'm asking</p> <p>25 you, Ma'am, at this point is whether there was</p>	<p>1 always the same, correct, that is there is no</p> <p>2 evidence of any asbestos of -- scratch that.</p> <p>3 The answer provided by Johnson and</p> <p>4 Johnson was always the same, there's no evidence of</p> <p>5 any amount of any asbestos in any of Johnson and</p> <p>6 Johnson cosmetic products, correct?</p> <p>7 A There was no asbestos in Johnson and</p> <p>8 Johnson products, correct.</p> <p>9 Q Now, Johnson and Johnson specifically told</p> <p>10 the FDA that there was no asbestos or tremolite in</p> <p>11 Johnson's Baby Powder, correct?</p> <p>12 A Can you repeat that question?</p> <p>13 Q Yes, Ma'am. Johnson and Johnson told the</p> <p>14 FDA that there was no asbestos or tremolite in any</p> <p>15 Johnson's Baby Powder, correct?</p> <p>16 A I don't recall seeing that, no.</p> <p>17 Q 464. So you have in front of you a memo</p> <p>18 from July 27, 1971, about the special talc project</p> <p>19 and it memorializes a meeting that was held with</p> <p>20 Johnson and Johnson and the FDA, correct?</p> <p>21 A Yes.</p> <p>22 Q And you reviewed this in preparation for</p> <p>23 today's deposition?</p> <p>24 A Yes.</p> <p>25 Q The memo says a Dr. Weisler worked for the</p>

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<p>1 FDA, correct?</p> <p>2 A Yes.</p> <p>3 Q Wanted to know if tremolite or fibrous talc was found. We stated that our information is that no asbestos was found and that we will have a full, detailed report on the findings in about a week, correct?</p> <p>4 A Yes.</p> <p>5 Q Now, as a follow up to that, you, Johnson and Johnson told the FDA had that you had conclusive proof that there was no asbestos in Johnson's Baby Powder, correct?</p> <p>6 A I don't recall those exact words, but we did send extensive reports to the FDA about the testing qualification of the materials.</p> <p>7 Q 474 is a memo a couple weeks later, September 21, 1971, from Johnson and Johnson to the FDA. Do you see that?</p> <p>8 A Yes.</p> <p>9 Q And what you state on the second page is, "It is seen that the data conclusively proves that Johnson's Baby Powder is free of asbestos," correct?</p> <p>10 A Yes.</p> <p>11 Q And that you further told the FDA that there was not ever a shred of evidence that there</p>	<p>1 Q 475 is another letter from 1973 written by Johnson and Johnson to the FDA, correct?</p> <p>2 A Yes.</p> <p>3 Q And it talks about Shower to Shower as a product, correct?</p> <p>4 A Yes.</p> <p>5 Q And what you state on the second page of your letter to the FDA is, "It should be noted that the talc in our medicated powder is from our Vermont mine source which has been exhaustively studied and reported on in various previous submissions. It was shown to be free of detectable asbestos by all available methods of analysis." Correct?</p> <p>6 A That is correct. This says it is from the mine source. It doesn't say it is a mine survey. That's where your question before was a little bit confusing.</p> <p>7 Q Johnson and Johnson told the FDA that "the source of the talc used in the powder from their Vermont mine was free of any detectable asbestos by all available analysis and methods." Correct?</p> <p>8 A You are misstating that. It says, "It should be noted that talc in our medicated powder is from our Vermont mine which has been exhaustively studied. It was shown to be free of detectable</p>
<p>1 was asbestos in either Johnson's Baby Powder or Shower to Shower, correct?</p> <p>2 A That sounds familiar.</p> <p>3 Q Do I need to show you that document?</p> <p>4 A Sure, go ahead.</p> <p>5 Q 483. This is a memo concerning a meeting you had with the FDA in 1972, correct?</p> <p>6 A Yes.</p> <p>7 Q And what you told the FDA was that there wasn't a shred of evidence to support the idea that either Johnson and Johnson's Baby Powder or Shower to Shower contained any chrysotile asbestos, correct?</p> <p>8 MR. SMITH: Objection.</p> <p>9 A Correct.</p> <p>10 Q Not a shred of evidence?</p> <p>11 MR. SMITH: Objection.</p> <p>12 A Yes.</p> <p>13 Q You told the FDA that there was absolutely no evidence of asbestos in any of the mines the baby powder came from using every method of analysis.</p> <p>14 You told them that, correct?</p> <p>15 MR. SMITH: Objection.</p> <p>16 A I don't recall saying that about the maintenance per se.</p>	<p>1 asbestos by all methods of analysis."</p> <p>2 It is unclear to me whether that's referring to the mine or the medicated powder. We have to go to the Pooley reports to determine what exactly was done in the Vermont mines.</p> <p>3 Q You don't know what this refers to as you sit here?</p> <p>4 A I'm saying I'm not sure of the "it." It is sentence structure whether the it refers to the powder or the mine.</p> <p>5 If we are going to talk about the mine, I would say that we should look specifically at the report of the mine.</p> <p>6 Q I'm going to do that later today. I want to know what you told the FDA and you represented.</p> <p>7 You understand that part of the purpose today is to determine whether Johnson and Johnson told the FDA the whole truth. You understand that, correct?</p> <p>8 MR. SMITH: Objection.</p> <p>9 A Yes, I do understand it. That's why I'm referring to that more comprehensive mine survey that was done.</p> <p>10 Q All I want to know now is exactly what Johnson and Johnson represented to the FDA. Then we will get to what they actually told the FDA. Do you</p>

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<p>1 follow me?</p> <p>2 A No, I don't know the differences between 3 represented and told.</p> <p>4 Q Let's focus on what Johnson and Johnson 5 represented in terms of whether the talc mine or any 6 of the products contained asbestos. That is what 7 I'm focusing on, okay?</p> <p>8 A Okay.</p> <p>9 Q We are on the same page?</p> <p>10 A Um-hum.</p> <p>11 Q Is it your testimony that Johnson and 12 Johnson told the FDA that there might be asbestos in 13 the Vermont mines that it owned?</p> <p>14 A So we will have to go to the Pooley report 15 to look at the mine. The products made from ore 16 that came out of the Vermont mines is free of 17 asbestos, based on the limits of detection of the 18 methodology used. You are mixing two things, 19 product and mines.</p> <p>20 Q No, I'm not mixing anything. You are 21 mixing it in your answer. I'm asking you 22 specifically did Johnson and Johnson represent to 23 the FDA that the mines that it owned, that the talc 24 came from, that was used in its products, did it tell 25 the FDA that those mines were free of asbestos?</p>	<p>1 MR. SMITH: Objection.</p> <p>2 A My honest answer is we have a very 3 comprehensive report here that we can look at and 4 see exactly what was said, and that was sent to the 5 FDA.</p> <p>6 Q Other than looking at the report, which we 7 are going to get to, you don't know, you, Johnson 8 and Johnson, don't know as you sit here today 9 whether you ever represented to the FDA specifically 10 that there's no evidence of asbestos in the mines 11 used to manufacture baby powder or Shower to Shower?</p> <p>12 MR. SMITH: Objection.</p> <p>13 A I don't know what -- I keep giving, you 14 have the answer, which is in the report that 15 went to the FDA, and we can look at that point and 16 see exactly what it says.</p> <p>17 Q Does the report, Ma'am, as you sit here 18 today, do you have any evidence, do you have any 19 recollection of seeing a report to the FDA that 20 admitted that there was asbestos in any of the mines 21 used to manufacture baby powder or Shower to Shower?</p> <p>22 MR. SMITH: Objection.</p> <p>23 A Would you like to look at the report?</p> <p>24 Q I'm asking you what you know, Ma'am. We will 25 get to the reports later. Do you have any</p>
<p>1 MR. SMITH: Objection.</p> <p>2 A We sent the report from Dr. Pooley of the 3 Italian mines and Vermont mines to the FDA. We will 4 have to go to those reports to see exactly what it 5 says. I have those here, I'm happy to pull those 6 out.</p> <p>7 Q Ma'am, I'm asking you a very specific 8 question. Did Johnson and Johnson represent to the 9 FDA that the mines that were used to make Johnson's 10 Baby Powder or Shower to Shower were free of 11 asbestos? That is my question. Did you make that 12 representation?</p> <p>13 A I don't recall any specific statement to 14 that effect, but I do know that we sent 15 comprehensive surveys of the mines that were used to 16 the FDA and I have those here and I'm happy to review 17 them.</p> <p>18 Q I'm going to do that with you. All I want 19 to know, the only thing I'm focusing on is what you 20 told the FDA about whether the mines that you own 21 that were used for baby powder and Shower to Shower, 22 whether you ever told them they had asbestos anywhere 23 in the mine, and your answer is what?</p> <p>24 MR. SMITH: Objection.</p> <p>25 Q You don't know?</p>	<p>1 independent memory?</p> <p>2 A I have an independent memory that reports 3 are complex and they have multiple testing in them 4 and you have to go to the conclusion to see what the 5 report said to understand the meaning of what was 6 communicated between J and J and the FDA.</p> <p>7 Q Do we agree, as you sit here, you don't 8 have any independent knowledge of what was 9 represented to the FDA about whether the mine that 10 was used to manufacture baby powder or Shower to 11 Shower had asbestos in it?</p> <p>12 MR. SMITH: Objection.</p> <p>13 Q You have no independent recollection?</p> <p>14 MR. SMITH: Objection.</p> <p>15 A My recollection is based on the report 16 that was sent to the FDA, which I would be very 17 happy to review with you.</p> <p>18 Q Without looking at that report, what is 19 your recollection?</p> <p>20 A My recollection is it is a very complex 21 report, but that material there comes out of that 22 mine that is used to make baby powder does not 23 contain asbestos.</p> <p>24 MR. SMITH: What time do we want to 25 break for lunch?</p>

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<p>1 MR. PLACITELLA: Why don't you give 2 me another fifteen minutes and then we can break. 3 4 Q Am I correct you told the FDA that there 5 isn't a single instance where a test result showed 6 there was chrysotile asbestos in any Johnson and 7 Johnson product? 8 A No product released to the market ever 9 contained chrysotile asbestos. 10 Q My question is, did you affirmatively 11 represent to the FDA that there is not a single 12 instance, not a single report of chrysotile in any 13 of the Johnson and Johnson products? 14 A We have said over and over again there's 15 no asbestos in our products, so I would say that 16 includes chrysotile asbestos. 17 Q A single instance? Not one? 18 A No product has been released to the market 19 there contains a single instance of asbestos. 20 Q Now, you understand that tremolite is 21 something known as an amphibole? 22 A Yes. 23 Q Did you represent specifically to the FDA 24 that there are no amphiboles or serpentine materials 25 ever detected in a Johnson and Johnson product?</p>	<p>1 been found in any testing ever. Correct? 2 MR. SMITH: Objection. 3 A This refers to -- hold on, let me find the 4 page. This refers to the worldwide survey for body 5 powders. This is off the shelf Johnson and Johnson 6 body powders that are collected all over the 7 world and tested for asbestos and that's 8 correct, that no asbestos has ever been found in 9 those materials. 10 Q Ever? 11 A Referring specifically to the worldwide 12 surveys of Johnson and Johnson baby powders that are 13 taken off the shelf and tested for asbestos, and 14 during that program no asbestos has been detected in 15 materials that is out for consumers to buy. 16 Q So no matter where they got the asbestos 17 anywhere in the world, it is Johnson and Johnson's 18 position that there's never been a single test 19 showing that there's asbestos in the Johnson and 20 Johnson products, correct? 21 MR. SMITH: Objection. 22 A So you said we went around the world to 23 get asbestos? We went around the world to get 24 Johnson and Johnson baby products off the shelf, 25 test for asbestos and those have not shown asbestos</p>
<p>1 A No, because that wouldn't be correct. 2 Q Exhibit 60 is the submission that your 3 trade association gave to the FDA, which included a 4 letter from Johnson and Johnson, correct? 5 A It is a little hard to read. It is so 6 tiny. I'm looking. Give me one minute, please. 7 Yes, I've seen this. 8 Q And can you go to the part of the 9 submission that is authored by Johnson and Johnson, 10 the March 19, 1976 letter. 11 A I see March 14th. Hold on. 12 Q March 15th. 13 A March 15th. You said 19th. 14 Q Okay. And what you say to the FDA, no 15 amphibole materials have been detected, correct? 16 A That's what it says beginning in October 17 1973 to whatever date in 1976. 18 Q Right. Now, I'll show you 492. 492 is 19 your March 17, 2016 letter to the FDA on Johnson and 20 Johnson letterhead, correct? 21 A Yes. 22 Q And in that letter, what you did is in the 23 face of lawsuits and verdicts, you went back to the 24 FDA and told them, again, that from the perspective 25 of Johnson and Johnson, no asbestos structures have</p>	<p>1 in that material that is out on the shelf for 2 consumers to buy. 3 Q That's my question. It is your position 4 that no matter where you go in the world, if you 5 tested the Johnson Baby Powder, it has no evidence 6 of asbestos and never did. That's your position, 7 correct? 8 MR. SMITH: Objection. 9 A That is the facts related to this 10 worldwide survey we shared with the FDA in March of 11 2016. 12 Q It had no asbestos and never did, correct? 13 A It says no asbestos was found in that 14 worldwide survey. 15 Q And never did? 16 A It does not say never did. 17 Q Well, was it ever? 18 A Was it ever what? 19 Q Found asbestos in any Johnson's Baby 20 Powder? 21 A Not production product that's on the shelf 22 for consumers to buy, no. 23 Q So it is Johnson and Johnson's position as 24 we are sit here today that no testing ever showed 25 any amounts of any asbestos in any Johnson and</p>

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<p>1 Johnson consumer product, correct?</p> <p>2 MR. SMITH: Objection.</p> <p>3 A When you refer to Johnson and Johnson consumer product, that is product that has been released to the market. No, there's not been asbestos in that product that has been tested by legitimate means.</p> <p>4 Q When you stay legitimate means, what do you mean by that?</p> <p>5 A Some individuals have bought products off of Ebay and other sources and tested them and claimed to have found asbestos, and I believe that is incorrect methodology and unreliable test results.</p> <p>6 Q And you are competent to testify about the methodology used by experts testing asbestos?</p> <p>7 A No, but I'm competent to testify if you buy something on Ebay that's been opened in an environment that is uncontrolled, you cannot rely on those results.</p> <p>8 Q What about testing products that are in Johnson and Johnson's historical files? Is that a legitimate methodology?</p> <p>9 A It is a legitimate source of material, but the methodology is another issue.</p>	<p>1 happy, welcome to come look at them? Did you ever tell them that?</p> <p>2 A In effect, we have.</p> <p>3 Q And who did you tell specifically that?</p> <p>4 A And who said that?</p> <p>5 A Until June of this past year a number of individuals, myself included, met with the FDA and discussed test results and asbestos testing in our quality assurance system that starts qualifying of the mines and goes through multiple testing to the finished products, and that they are more than welcome to see any of those tests.</p> <p>6 They didn't want to see the tests.</p> <p>7 They wanted our specifications and our methodology and so forth, all of which was sent to them.</p> <p>8 Q So before -- did you say this year?</p> <p>9 A You asked me if we ever had --</p> <p>10 Q I want to get the date right. This year?</p> <p>11 A 2018.</p> <p>12 Q So before June of 2018, have you ever made all of your test results available for inspection by the FDA?</p> <p>13 A The FDA can inspect us at any time and we would have certainly worked with them and cooperated to make whatever tests results they wanted</p>
<p>1 Q One more and we will break for lunch.</p> <p>2 498 comes from an advertisement that</p> <p>3 you ran in December of last year all over the United States. You have seen this before, correct?</p> <p>4 A Yes.</p> <p>5 Q You say, "We know that we have always cooperated fully and openly with the FDA and other regulators and have given them full access to our testing, our talc testing results." Do you see that?</p> <p>6 A Yes.</p> <p>7 Q That means you gave them all the test results in your possession?</p> <p>8 A Full access. We have not sent them every single test result. I don't think they would appreciate that very much.</p> <p>9 Q So who decided what test results were going to be sent to the FDA and which ones were not?</p> <p>10 Who made that decision?</p> <p>11 A Full access means that if there's any issue to be discussed where test results would be helpful, they absolutely would share those results with the FDA.</p> <p>12 Q Did you ever tell the FDA that we have other test results we didn't send you, but you are</p>	<p>1 available to them.</p> <p>2 Q Ma'am, before June of 2018, had you ever told the FDA that you had test results related to asbestos in talc that you did not provide them?</p> <p>3 A No, not that I know of.</p> <p>4 Q You also say in your advertisement, "We know that we did not hide anything. Our openness and collaboration with the FDA and regulatory agencies is well documented." Correct?</p> <p>5 A Correct.</p> <p>6 Q The books you have in front of you, let's identify them and we will go take a break for lunch and I'll look at them at lunchtime. Okay?</p> <p>7 So tell me what is in each of the books generally that you have in front of you.</p> <p>8 A So P-3 is volume 1 and contains communications back and forth between Johnson and Johnson and the FDA and some other contextual documents are included as well.</p> <p>9 Volume 2 is the March 2016 communication that we sent to the FDA and all of the associated attachments. In addition, there's a July 2018 communication in volume number 2.</p> <p>10 Volume 3 are contextual documents that indicate what was going on at different points</p>

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<p>1 in time during the history of talc and asbestos 2 starting in the late '60s up until present day, 3 giving you context for understanding the development 4 of asbestos testing, citizens petitions and other 5 related events.</p> <p>6 Q That's it?</p> <p>7 A That's it.</p> <p>8 Q In these three volumes, does that include 9 all the information that you provided to the FDA 10 concerning the testing of Johnson and Johnson talc 11 for asbestos?</p> <p>12 A As far as I'm aware, yes, it does.</p> <p>13 MR. PLACITELLA: This is a good place 14 to take a break.</p> <p>15 THE VIDEOGRAPHER: The time is 16 approximately 12:32 p.m. We are going off the 17 record.</p> <p>18 (Luncheon recess taken)</p> <p>19</p> <p>20 THE VIDEOGRAPHER: We are back on the 21 record. The time is approximately 1:12 p.m.</p> <p>22</p> <p>23 CONTINUED DIRECT BY MR. PLACITELLA:</p> <p>24</p> <p>25 Q Dr. Nicholson, I asked this morning, and I</p>	<p>1 Q There's no testing done on Johnson and 2 Johnson Baby Powder related to the 1980s, correct?</p> <p>3 A Correct. Then there's -- one last 4 document, which is tab 13, which is the McCrone 5 letter that says that for the previous fifteen 6 years, and this letter is dated May 1987, that they 7 had been testing routinely material for a number of 8 companies, including Johnson and Johnson over the 9 years, and have the product is free of asbestos, 10 second to the last line. That is not FDA, but 11 that's an independent organization testing talc for 12 industry.</p> <p>13 Q Right. But they were paid by Johnson and 14 Johnson.</p> <p>15 A They were.</p> <p>16 Q So my question this morning was, you don't 17 have any evidence, as you sit here today, of any 18 test run by the FDA of Johnson talc products from a 19 Vermont source after 1979, correct?</p> <p>20 A Correct. The FDA didn't do their own 21 testing. They, too, used outside sources.</p> <p>22 Q But there was no testing by any outside 23 source hired by the FDA of Vermont based products 24 after 1979, correct?</p> <p>25 A That is correct. We have a calculations</p>
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<p>1 know you looked it over at a break, I asked you 2 questions about the FDA itself testing for 3 Vermont sourced products, and you said you believe 4 there was testing in the '84, '86, but you weren't 5 sure what they tested for. Did you find what you 6 were referencing?</p> <p>7 A I found three different things, and so one 8 is a 1986 FDA petition denial, which is more 9 mathematical analysis of some theoretical exposure 10 limits.</p> <p>11 So the one thing of importance was 12 around the exposure risk assessment.</p> <p>13 Q I'm familiar with that document, but that 14 had nothing to do with the physical testing of a 15 Johnson and Johnson product for asbestos, correct?</p> <p>16 A That is correct. Then there was the 17 Boundy Study, which did review --</p> <p>18 Q That's on what tab and what exhibit?</p> <p>19 A This is tab 9 of P-5. This refers to 20 NIOSH, which is the National -- I don't remember 21 what NIOSH stands for.</p> <p>22 This is from Maryanne Boundy and 23 others from Environmental Health Sciences from 24 Harvard. This is in the late '70s. They looked at 25 bulk Vermont talc.</p>	<p>1 by FDA and the McCrone letter saying talc is 2 free from asbestos for fifteen years. But you are 3 correct, FDA, not until 2009, did a survey of 4 cosmetic talc.</p> <p>5 Q And when the FDA did their survey of 6 cosmetic talc in 2009, Johnson and Johnson was no 7 longer using a Vermont mine as the source for its 8 cosmetic talc, correct?</p> <p>9 A That's correct. In 2003 we switched to 10 China.</p> <p>11 Q So from 1979 until any time thereafter, 12 the FDA never did a test to determine whether the 13 Johnson and Johnson talc contained asbestos that was 14 sourced from a Vermont mine, true?</p> <p>15 MR. SMITH: Objection.</p> <p>16 A So FDA did not do a test of Johnson and 17 Johnson product. That is correct, but Johnson and 18 Johnson was testing their product, McCrone was 19 testing the product.</p> <p>20 We know it was free of asbestos, but 21 you are correct, Johnson and Johnson did not test 22 the product that I'm aware of.</p> <p>23 Q So without everything else stuffed in, all 24 I want to know is as we sit here today can we agree 25 that there was no testing done by the FDA of any</p>

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<p>1 Johnson and Johnson product that came from a Vermont 2 mine after 1979?</p> <p>3 A Not that I'm aware of that we have 4 evidence in these documents.</p> <p>5 Q So any time after 1979, any test results 6 that were considered by the FDA were done for 7 Johnson's Baby Powder, were done by Johnson and 8 Johnson or the experts that it hired, correct?</p> <p>9 A I can't speak to others outside of that 10 circle, for example, academics that did testing on 11 product that would have been Johnson and Johnson 12 product. But in the documents prepared for today, I 13 have just the McCrone letter saying free from 14 asbestos and that includes Vermont talc.</p> <p>15 Q So from your perspective in the FDA 16 assessing the safety of the Johnson and Johnson 17 product in terms of whether it ever contained 18 asbestos, the only test result you can point to 19 after 1979 is the McCrone letter that you 20 referenced?</p> <p>21 A Well, we have internally thousands and 22 thousands of test results.</p> <p>23 Q That wasn't my question, Ma'am. My 24 question was test results considered by the FDA and 25 assessing the safety of the Johnson and Johnson's</p>	<p>1 I'm trying to be very specific in my answer.</p> <p>2 Q The answer is that for Vermont talc, the 3 only test you gave to the FDA and that you 4 understand was considered by the FDA was the 1987 5 McCrone letter in terms of whether the Johnson 6 product was asbestos free, correct?</p> <p>7 A That the FDA had, that's correct, but 8 again, we were following the J41 standard.</p> <p>9 Q We will get to that. Let me ask you some 10 more questions about the binder before we get to the 11 standard.</p> <p>12 The binder, I don't know which one it 13 was, had an expert report from a lawsuit from a Mr. 14 Bailey. You gave that to the FDA?</p> <p>15 A No. The reason we included that, you 16 recall I explained about the binders is that this 17 was also to create context so those communications 18 and why we been talking about any given thing 19 would be understood.</p> <p>20 Dr. Bailey gave a very comprehensive 21 review of what was done and how things progressed 22 from the '60s through to more recent times. That's 23 why it was included.</p> <p>24 Q But his report was never given to the FDA?</p> <p>25 A Not that I'm aware of.</p>
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<p>1 talc products, the only test results that you have 2 that was supplied to the FDA and considered by the 3 FDA after 1979 was the McCrone 1987 letter, true?</p> <p>4 A So I'm confused by your question because 5 it was the 2009 survey that included Johnson and 6 Johnson baby products and raw materials.</p> <p>7 Q Let me rephrase it then. It is my fault. 8 From 1979 forward, the FDA had no 9 information in its possession that you are aware of 10 concerning Johnson's talc products sourced from a 11 Vermont mine on the issue of asbestos content, other 12 than the McCrone letter from 1987, correct?</p> <p>13 A Well, they had information we would have 14 been following the J41 standard that basically 15 required us to test everything for asbestos. So we 16 were in compliance with the standard and therefore, 17 testing regularly for asbestos.</p> <p>18 Q Ma'am, my question to you is after 1979, 19 the only document that you gave to the FDA to 20 support the proposition that Vermont sourced talc 21 products were asbestos free was the McCrone letter 22 from 1987, true?</p> <p>23 A That I recall related to Vermont talc.</p> <p>24 Q So the answer is yes?</p> <p>25 A You put so many qualifications in there,</p>	<p>1 Q So if we wanted to be very specific now, 2 as to what scientific information you provided to 3 the FDA on the issue of whether there was ever 4 asbestos found in any Johnson and Johnson talc 5 product, they are included in what binder?</p> <p>6 A They are in this binder.</p> <p>7 Q When you say this binder, be specific.</p> <p>8 A Volume 1, P-3.</p> <p>9 Q So we don't have to worry ourselves, binder 10 2 or 3 on this specific topic of testing information 11 that you gave to the FDA concerning asbestos and 12 Johnson talc, correct?</p> <p>13 A Except volume 2 contains the entirety of 14 the two most recent communications to the FDA.</p> <p>15 Q So let me be specific then. Other than 16 the communications you had with the FDA after 2017, 17 all of the scientific information that you provided 18 to the FDA concerning whether the Johnson's Baby 19 Powder contained asbestos at any point in time, or 20 Shower to Shower, is contained in volume 1. Is that 21 fair?</p> <p>22 A Yes.</p> <p>23 Q Except you said 2017, not 2016.</p> <p>24 Q 2016. Okay.</p> <p>25 Now, 457 is a document, looks like</p>

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<p>1 from 1977, listing all of the information you 2 supplied to the FDA as of 1977. Is that true? 3 A That's true. And this is contained in 4 this binder. 5 MR. SMITH: Which binder? 6 A Volume 1, P-3. 7 Q So everything that is on that list is 8 contained in binder number 1? 9 A Everything we could find in our records is 10 contained herein. There are some documents that we 11 can note that we couldn't find that were referenced in 12 other material with the original documents was not 13 in our records and could not be located. 14 Q Did somebody go back and look for the 15 paper and see if there was a paper file of the 16 original document? 17 A Yes. 18 Q That doesn't exist? 19 A Not that we have found. 20 Q Can we agree that no one at the FDA knew 21 more about the flaws or shortcomings in the asbestos 22 testing methods than Johnson and Johnson and the 23 experts that it hired? 24 MR. SMITH: Objection. 25 A I can't speak to what the FDA knew or</p>	<p>1 1973, attended by Johnson and Johnson. If you go to 2 the page where you see where it says, meeting of talc 3 group March 21, 1973 and it says Dr. Ashton from 4 Johnson and Johnson was present? 5 A Yes. 6 Q It talks about what Dr. Ashton discussed 7 at the meeting on the third page. It says Dr. 8 W.H. Ashton, J and J, began discussion of 9 methodology for determining asbestos or fibers by 10 reviewing J and J experience with different 11 instruments. Least sensitive is optical microscope. 12 Next in order of increasing 13 sensitivity and cost and difficulty to run are x-ray 14 scan, x-ray step scan, electron scan, electron 15 differential scan and DPA differential thermal 16 atomizer. Do you see that? 17 A Yes. 18 Q And what Johnson and Johnson ultimately 19 urged the FDA to adopt what was the two worst in 20 this list, right, the least sensitive, the optical 21 microscope the X-ray diffraction, correct? 22 MR. SMITH: Objection. 23 A You are mischaracterizing that. You are 24 looking at them as individual tests, and it has been 25 discussed in numerous documents that using multiple</p>
<p>1 didn't know. 2 Q Do you understand that in the process of 3 trying to come up with a way to reliably test for 4 asbestos, that the FDA wanted a method that had a 5 sensitivity greater than 1 percent. You know that, 6 correct? 7 MR. SMITH: Objection. 8 A At one point of the discussions that 9 one percent number was contemplated. The actual 10 sensitivity is significantly lower than that. 11 Q Am I correct that Johnson and Johnson 12 recommended to the FDA a testing method that Johnson 13 and Johnson knew would not find amphiboles, 14 including tremolite, at low levels? 15 A I don't know what you are referring to. 16 Q Well, am I correct that of all the testing 17 methods that were available for the determination of 18 whether there was asbestos or tremolite in Johnson 19 and Johnson talc, Johnson and Johnson urged the FDA 20 to pick the two worst methods for figuring that out? 21 A That is not correct. 22 MR. SMITH: Objection. 23 Q 489. I want to show you a document marked 24 April 18, 1973, business records of Whittaker, Clark 25 and Daniels memorializing a meeting of March 21,</p>	<p>1 tests, the correct multiple tests together, is what 2 gives you the best results. So you are 3 mischaracterizing what is being stated. 4 Q I'm not. All I'm asking you is ultimately 5 the two tests in combination that Johnson and 6 Johnson recommended that the FDA use were the two 7 least sensitive tests, according to Dr. Ashton, that 8 is, the optical microscope and the X-ray diffraction 9 method, right? 10 A Wrong. You are mischaracterizing that. 11 You have said in combination and then in combination 12 they are the best method. That's why they are in 13 the J41. 14 Q What Johnson and Johnson recommended was 15 first you use the X-ray diffraction and then, if 16 that comes up positive, you then you use the optical 17 microscope, correct? 18 A That's how you figure out if you have 19 asbestos in your sample. A step one screening. 20 Q They used the two least sensitive methods 21 as articulated by Dr. Ashton in this document, 22 correct? 23 A Not correct. You are totally 24 misunderstanding what is being said. 25 Q I don't think so. We are going to get to</p>

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<p>1 that. Do you see that?</p> <p>2 A I do.</p> <p>3 Q What it shows is from looking for</p> <p>4 tremolite, only one laboratory found tremolite using</p> <p>5 the CTFA method and six did not. Do you see that?</p> <p>6 A I do.</p> <p>7 Q That was tremolite that was spiked, in</p> <p>8 other words, they put the tremolite in the talc,</p> <p>9 correct, so you could see if they could find it,</p> <p>10 right?</p> <p>11 A That is correct.</p> <p>12 Q When they used the CTFA method, six out of</p> <p>13 seven couldn't find it using the CTFA method,</p> <p>14 correct?</p> <p>15 A Six out of seven reported a negative test.</p> <p>16 That's correct.</p> <p>17 Q Now, you are aware, are you not, that</p> <p>18 internally Johnson and Johnson actually wrote down</p> <p>19 that the CFTA method was not good enough and not</p> <p>20 sensitive enough to find low levels of tremolite.</p> <p>21 You are aware of that, right?</p> <p>22 MR. SMITH: Objection.</p> <p>23 A Are we still talking about this document?</p> <p>24 Q No, I'm asking you another question.</p> <p>25 A Okay.</p>	<p>1 was in cosmetic talc, correct?</p> <p>2 MR. SMITH: Objection.</p> <p>3 A So TEM was discussed extensively during</p> <p>4 the meeting and we are going back to that document</p> <p>5 you just showed me. But practical, reliable and</p> <p>6 sensitive. So if people did not have the machine for</p> <p>7 the testing, it could not be suggested and adopted</p> <p>8 as a universal standard for the industry.</p> <p>9 Q Yes, Ma'am. The answer to my question is</p> <p>10 Johnson and Johnson did not recommend to the FDA</p> <p>11 that the standard that should be adopted for testing</p> <p>12 talc for asbestos was TEM, correct?</p> <p>13 A I can't answer that question because it</p> <p>14 was a scientific discussion of many methods and</p> <p>15 there were multiple participants in the</p> <p>16 conversation.</p> <p>17 Johnson and Johnson wasn't in a</p> <p>18 position to have a definitive recommendation, but</p> <p>19 rather come to a consensus agreement with FDA and</p> <p>20 the industry partners.</p> <p>21 So you are asking me if they had</p> <p>22 a separate opinion. I have not seen any</p> <p>23 documents to that effect, but I've seen other</p> <p>24 documents discuss all of the various methods that</p> <p>25 were available, like the one we talked about a</p>
<p>1 Q You are aware that internally Johnson and</p> <p>2 Johnson had discussions where they acknowledged that</p> <p>3 the CFTA, J41 method was not good enough for the</p> <p>4 detection of low levels of tremolite, correct?</p> <p>5 A It is the CTFA, not the CFTA and we always</p> <p>6 use transmission electron microscopy adjunct, so that</p> <p>7 may have been discussed and perhaps validated while</p> <p>8 we continue to this day to use test TEM, which is</p> <p>9 the most sensitive method.</p> <p>10 Q You didn't recommend to the FDA to use</p> <p>11 TEM, your recommendation to the FDA was for the J41</p> <p>12 method, correct?</p> <p>13 A The Cosmetics Toiletry and Fragrance</p> <p>14 Association recommended the J41. We continued to do</p> <p>15 TEM.</p> <p>16 One of the major limitations at the</p> <p>17 time is that TEM was not universally available.</p> <p>18 We, however, had that equipment. We used all of</p> <p>19 that equipment all the time.</p> <p>20 Q That wasn't my question, please. We've</p> <p>21 got to finish this deposition, so if you could just</p> <p>22 answer my question.</p> <p>23 My question is this, that Johnson and</p> <p>24 Johnson did not recommend to the FDA that TEM be</p> <p>25 used for the testing to determine whether asbestos</p>	<p>1 minute ago.</p> <p>2 Q What was recommended by Johnson and</p> <p>3 Johnson and its trade association for the analysis</p> <p>4 of asbestos in talc was the CFTA J41 method,</p> <p>5 correct?</p> <p>6 MR. SMITH: Objection.</p> <p>7 A It is the CTFA J41 method, and the</p> <p>8 document you showed me a minute ago, the industry</p> <p>9 was continuing to look at that method and refining</p> <p>10 it to make sure it was accurate, reliable and</p> <p>11 practical.</p> <p>12 So not at that time did we definitively</p> <p>13 say this is the one and only standard, we are not</p> <p>14 going to evolve our thinking. This was something</p> <p>15 being actively tested and refined in 1977 and has</p> <p>16 been revisited since then. So I'm not sure what you</p> <p>17 are implying with the question.</p> <p>18 Q You were still using it in 1995, right?</p> <p>19 A Who is we?</p> <p>20 Q The CTFA Method. Johnson and Johnson.</p> <p>21 A We used that method. It is an industry</p> <p>22 standard and in addition, we do TEM testing.</p> <p>23 Q And internally you acknowledge, did you</p> <p>24 not, that the CTFA method was not sensitive enough</p> <p>25 to find low levels of tremolite. You acknowledge</p>

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<p>1 that.</p> <p>2 A That's true. Every test method has a limit 3 of detection, but we still use TEM, which increases 4 our abilities in sensitivity of our testing.</p> <p>5 Q Ma'am, all I'm asking you is internally 6 you acknowledged, you, Johnson and Johnson, that the 7 CTFA J41 method was not sensitive enough to find low 8 levels of tremolite, correct?</p> <p>9 MR. SMITH: Objection.</p> <p>10 A Every test method, combination of test 11 methods has their limits of detection, so that would 12 have been acknowledged by FDA, CTFA, Johnson and 13 Johnson and many others.</p> <p>14 Q So the answer to my question is internally 15 Johnson and Johnson acknowledged that the CTFA J41 16 method was not sensitive enough to find low levels 17 of tremolite when testing the powder, correct?</p> <p>18 A First of all, tremolite is not asbestos. 19 Second of all, the CTFA method, every method of 20 detection does have its limits. So everyone would 21 have acknowledged that, including J and J.</p> <p>22 Q In fact, when you were testing your 23 products in Great Britain, you specifically rejected 24 using the CTFA method, didn't you?</p> <p>25 A I have not reviewed that topic in</p>	<p>1 forward in this written by Dr. Pooley?</p> <p>2 A Yes.</p> <p>3 Q Do you see it actually says, and I blew it 4 up so you can read it. In the second paragraph, 5 "Incidents of disease among talc workers has been 6 closely linked to the mineralogic impurities found in 7 raw material such as asbestos minerals and quartz." 8 Do you see that?</p> <p>9 A I do.</p> <p>10 Q Was that fact ever discussed with Dr. 11 Hopkins by you internally at Johnson and Johnson?</p> <p>12 A No, because there's not asbestos contained 13 in any of the cosmetic talc mines that went into our 14 cosmetic products.</p> <p>15 Q We will get to that. Do you see in Dr. 16 Hopkins' memo, 5.2 fibrous amphiboles, where 17 he states, "the inhalation hazards of fibrous minerals 18 have long been recognized. The CTPA view is that 19 fibrous minerals should not be detectable in 20 cosmetic talc by state of the art methods."</p> <p>21 And then he goes on to say, "However, 22 in order to eliminate any hazards to the consumer, 23 which might arise from the need to interpret fiber 24 and shape dimensions and to facilitate routine 25 screening, the CTPA view is that if an amphibole is</p>
<p>1 preparation for today.</p> <p>2 Q You spoke to Dr. Hopkins, correct?</p> <p>3 A We didn't discuss that particular issue.</p> <p>4 Q Dr. Hopkins never told that you he 5 actually wrote a memo indicating that in Great 6 Britain they recommended against using the CTFA 7 method because it wasn't sensitive enough?</p> <p>8 A I haven't reviewed that to prepare for 9 today's deposition.</p> <p>10 Q Did Dr. Hopkins ever tell you that he was 11 of the opinion, and expressed it to Johnson and 12 Johnson in written form, that tremolite in any form 13 should not be allowed in cosmetic talc products?</p> <p>14 A I have not discussed that with Dr. 15 Hopkins.</p> <p>16 Q 357 is a December 21, 1995 memo from 17 John Hopkins entitled CTPA talc monograph. Do you 18 know what the CTPA was?</p> <p>19 A I think it is a toiletry fragrance group 20 in Britain, but I'm not positive.</p> <p>21 Q It is the British counterpart to the CTFA 22 in the United States, correct?</p> <p>23 A I don't know. I'm not familiar with them 24 as an organization.</p> <p>25 Q You mentioned Dr. Pooley. There's a</p>	<p>1 detected by x-ray diffraction, that batch of talc is 2 unacceptable for cosmetic use, whether or not 3 subsequent examination by optical or electron 4 microscopy shows the contaminant is not fibrous." 5 Were you aware that was being discussed at Johnson 6 and Johnson?</p> <p>7 A This isn't Johnson and Johnson. This is 8 the industry group in Britain. So they are just 9 saying take the first step of the J41 and no need to 10 do the second step.</p> <p>11 Q What they are basically saying is once you 12 are find tremolite, that's it. Don't use it. 13 That's what Dr. Hopkins says.</p> <p>14 A That is not what this says. This says 15 unacceptable for cosmetic use. And the reason they 16 are doing this is to make sure that it is a cheap, 17 basically quick way to do it. But you are going to 18 throw a lot of material out potentially without any 19 hazard to humans.</p> <p>20 Q Whether or not subsequent examination by 21 optical or electron microscope shows the 22 contamination is not fibrous. That is what he says, 23 correct?</p> <p>24 A That is correct.</p> <p>25 Q What does he say about whether Johnson and</p>

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<p>1 Johnson should be using this CTFA method in Great 2 Britain?</p> <p>3 A I haven't seen this document before, so I 4 haven't reviewed it. I don't know what he said.</p> <p>5 Q Go to Bates number 77498. Do you see 6 where I blew it up, he talks about the detection 7 limits for the J41 method and he says, "You should 8 use another method called the step scanning method." 9 Correct? What he states is you should use a method 10 beyond the J41 method, and he states the increased 11 sensitivity is critical for better detection of 12 amphiboles, which otherwise using XRD procedures 13 alone would go undetected. Members urged strongly 14 to use this increased sensitivity, if at all 15 possible, particularly in light of the various new 16 foreign talcs that are emerging in the marketplace." 17 Correct?</p> <p>18 A I don't see exactly where you pointed to. 19 Q Right where I have the -- I even pulled a 20 lateral for you. 21 A I see that. 22 Q So in Great Britain Dr. Hopkins was saying 23 use something more sensitive than the XRD. Did you 24 ever recommend to the FDA, and did you ever let the 25 FDA know that internally you were using a method in</p>	<p>1 This is a 1995 document. I would 2 have to review it to really understand what the 3 context for this was.</p> <p>4 Q Let me show you a document from 2001 5 marked Exhibit 361, identified as a memo from Rich 6 Zazenski to Donna Dennis, subject talc 7 specification. Luzenac, this is a Luzenac business 8 record. Am I correct that Luzenac was one of your 9 suppliers of talc?</p> <p>10 MR. SMITH: Objection.</p> <p>11 A Luzenac was the predecessor, I think, of 12 Imerys.</p> <p>13 Q They were a part of the trade association 14 that you were a member of, the CTFA?</p> <p>15 A Yes.</p> <p>16 Q They were part of the group that made 17 recommendations as to what testing methods should be 18 used to the FDA?</p> <p>19 MR. SMITH: Objection.</p> <p>20 A Whoever the supplier was at that time was 21 participating.</p> <p>22 Q Do you see where they state, "Additionally 23 we can discuss an asbestos specification option 24 which required that cosmetic talc does not contain 25 detectable asbestos when analyzed by a transmission</p>
<p>1 Great Britain that you were not recommending to the 2 FDA?</p> <p>3 A I'll go back and say we have always used 4 transmission electron microscopy, in addition to the 5 J41.</p> <p>6 So with regard to the sensitivity of 7 Johnson and Johnson's methods, we are very confident 8 with the sensitivity, even more sensitive than what 9 Dr. Hopkins notes here.</p> <p>10 I have not reviewed this document 11 before. I've not discussed it with Dr. Hopkins, so 12 I really don't know the context in which this was 13 discussed.</p> <p>14 Q In Great Britain Johnson and Johnson was 15 recommending an XRD procedure that was more 16 sensitive than the one that they were recommending 17 to the FDA, correct?</p> <p>18 A Again, I haven't had the opportunity to 19 discuss this with Dr. Hopkins. I had not seen this 20 before today.</p> <p>21 As we were talking about FDA 22 communications between Johnson and Johnson and FDA 23 regarding asbestos testing, and the J41 was a method 24 that was developed in the early '70s, based upon 25 what was practical and reliable at the time.</p>	<p>1 electron microscopy TEM. I think we all recognize 2 XRD, PCM and PLM are simply not sensitive enough to 3 provide complete assurance that talc is free of 4 detectable asbestos." Do you see that?</p> <p>5 A Yes, I do.</p> <p>6 Q Johnson and Johnson was aware of that, 7 correct?</p> <p>8 MR. SMITH: Objection.</p> <p>9 Q That "the XRD, PCM and PLM methods are 10 simply not sensitive enough to provide complete 11 assurance that talc is free of detectable asbestos."</p> <p>12 MR. SMITH: Objection.</p> <p>13 A If you look at the method, the J41 and the 14 sensitivity of that method, and it is covered in 15 that 1986 response to the citizen petition, it is 16 more sensitive, it can pick up asbestos even more 17 sensitive than what is in the environment.</p> <p>18 In other words, if you find any 19 asbestos using those methods, it is more likely to 20 come from the air than it is from that sample.</p> <p>21 So I see what it is saying about 22 increased sensitivity using different methodologies, 23 and that's why the would be important for me to 24 speak to Dr. Hopkins to understand the context.</p> <p>25 What are they looking for there, when you have an</p>

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<p>1 environmental level that's many, many times higher 2 than what your sensitivity is you that are striving 3 for. It is a strange line of discussion, so I think 4 the context is critical.</p> <p>5 Q What was my question Ma'am? 6 MR. SMITH: Objection. 7 A Did I know there was more sensitivity than 8 what was currently being used to pick up asbestos. 9 Q No. That's not what I asked. I move to 10 strike your entire statement, Ma'am. Please answer 11 this question. This is the question I'm asking 12 you.</p> <p>13 Was Johnson and Johnson aware that 14 the XRD and the PLM method are not sensitive enough 15 to provide complete assurance that talc is free of 16 detectable asbestos? Was Johnson and Johnson aware 17 of that?</p> <p>18 MR. SMITH: Objection. 19 A I'm going to disagree that is it a correct 20 statement based on what I've seen in the 1986 FDA 21 response to the citizens petition. So why would you 22 get more sensitive testing than would be -- more 23 sensitive than what's in the environment? 24 That's the part that doesn't make 25 sense.</p>	<p>1 We don't need a more sensitive method 2 based on that analysis. That is why I would like to 3 talk to Dr. Hopkins and understand the context for 4 this discussion.</p> <p>5 Q So you are not able to testify here today 6 without having another conversation with Dr. 7 Hopkins. Is that what you are saying? 8 MR. SMITH: Objection. 9 A I have provided you with the document I'm 10 making reference to. 11 Q I'm going to get to that, I promise you. 12 MR. SMITH: Don't talk over the 13 witness. 14 Q I promise you. I'm asking you, Ma'am, do 15 you need to speak to Dr. Hopkins again before I talk 16 to you more about this document? 17 MR. SMITH: Were you finished with 18 your last answer? 19 A I don't recall. 20 MR. SMITH: Can you read back where 21 she was in her last answer before opposing counsel 22 talked over her. 23 MR. PLACITELLA: I'm going to 24 withdraw that question and ask you this question. 25 Q Ma'am, in order to answer any more</p>
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<p>1 Q You do not agree with this statement? 2 A The method may be -- there may be a more 3 sensitive method, but if the ambient air and the 4 water and everything, there's more asbestos in the 5 environment than you are trying to find here with a 6 testing method. It doesn't make sense to me. 7 That's what I'm saying. 8 Q Ma'am, respectfully again, I move to 9 strike your testimony. You testified in the 10 beginning of this deposition that you are not a 11 geologist and you are not an expert in asbestos 12 testing. 13 All I'm asking you, Johnson and 14 Johnson, is whether you agreed that the SRD and PLM 15 are not sensitive enough to give complete assurance 16 that talc is free of detectable asbestos. If you 17 don't agree, say it. If you do agree, say it. We 18 don't need a speech. 19 MR. SMITH: Objection, ignore those 20 comments. 21 A I appreciate that you don't like my answer 22 because we don't need a more sensitive method and 23 that's covered very specifically in that 1986 24 response to the citizens petition that I made 25 reference to earlier.</p>	<p>1 questions about detection methods, do you need to 2 speak with Dr. Hopkins? That is all I'm asking. 3 A No. 4 Q Can we agree that Johnson and Johnson and 5 the CTFA understood that the J41 method was not 6 sensitive enough for testing for chrysotile 7 asbestos? 8 MR. SMITH: Objection. 9 Q Can we agree to that? 10 MR. SMITH: Objection. 11 A No. 12 Q 266. I'm going to show you what's been 13 marked October 31, 1972 on Johnson and Johnson 14 letterhead. 15 MR. SMITH: I think you misspoke. 16 Q October 31, 1972? 17 MR. SMITH: This document has been 18 marked Exhibit 266. 19 MR. PLACITELLA: You are correct. 20 MR. SMITH: It is a letter. 21 MR. PLACITELLA: You are correct. 22 266. 23 Q The subject is analysis of Johnson's Baby 24 Powder for chrysotile asbestos. Do you see that? 25 A Yes.</p>

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<p>1 Q It talks about using the X-ray diffraction 2 method, correct? 3 A Yes. 4 Q What Johnson and Johnson says is that 5 method has been demonstrated that it was possible to 6 detect chrysotile and talc at a level of 2 to 3 7 percent by weight, correct? 8 MR. SMITH: Objection. 9 A Yes. 10 Q Am I correct that the FDA wanted to 11 regulate chrysotile asbestos, but Johnson and 12 Johnson took the position that was no reason to do 13 so because there was never no evidence ever that 14 there was asbestos chrysotile in Johnson's talc? 15 MR. SMITH: Objection. 16 A That's correct, because chrysotile is an 17 industrial asbestos. It is not found with talc in 18 the cosmetic mines. 19 Q So what Johnson and Johnson told the FDA 20 was there's no reason for you to regulate it 21 because there was no chrysotile ever found in any 22 mine that was the source of Johnson's Baby Powder, 23 correct? 24 MR. SMITH: Objection. 25 A Chrysotile is an environmental issue. So</p>	<p>1 when they were working out this industry standard 2 for asbestos testing. 3 Q You know that what Johnson and Johnson 4 ultimately did was try to discourage the FDA from 5 using that method, right? 6 A I'm not aware of that. 7 Q You are not aware as you sit here today 8 that Johnson and Johnson's own experts recommended 9 to them repeatedly that the pre-concentration method 10 be been used by Johnson and Johnson? 11 A No. I'm not aware of that. 12 MR. SMITH: Objection. 13 Q You have in front of you a memo from 14 February 26, 1973 to Mr. Ashton at Johnson and 15 Johnson from the Colorado School of mines. Do you 16 see that? 17 A Yes. 18 Q Have you ever seen this document before? 19 A I don't specifically recall that I have. 20 Q The Colorado School of Mines is one of the 21 entities that you relied upon when you were 22 communicating with the FDA concerning the testing of 23 asbestos in baby powder, correct? 24 A Yes. 25 Q Do you see at the top it talks about</p>
<p>1 it is an EPA regulated material. So that's correct, 2 it should not be regulated by the FDA. 3 Q I know from reading your prior testimony 4 you have been asked questions about the methodology 5 that Johnson and Johnson considered called the 6 pre-concentration method. Do you know what I'm 7 talking about? 8 A Yes. 9 Q And do you understand that at one point in 10 time the FDA was considering using the 11 pre-concentration method for testing for asbestos in 12 talc, correct? 13 A Correct. 14 Q And that NIOSH actually recognized the 15 viability of that methodology, correct. You knew 16 that? 17 A No, I wasn't aware of that. And Johnson 18 and Johnson's own experts recommended that it adopt 19 or use the pre-concentration method for determining 20 whether there was asbestos in Johnson and Johnson 21 talc, correct? 22 MR. SMITH: Objection. 23 A I don't know that, but I do know that 24 Johnson and Johnson offered to explore the 25 concentration method with the group during the '70s</p>	<p>1 sample grounded talc ore separated using a 2 centrifuge? I colored it so you can see. 3 A Yes. 4 Q That's a pre-concentration method, 5 correct? 6 A I don't know that is specifically the 7 pre-concentration method. It is a concentration 8 method, yes. 9 Q And when they did that, if you go to the 10 page that references February 26, 1973, according to 11 this document when that method was used, the 12 Colorado School of Mines found tremolite and 13 actinolite. Do you see that? 14 A Yes. 15 Q Do you see where it says relative to 16 possible asbestos type minerals the above table 17 shows that samples 3071S contained slight traces of 18 tremolite, actinolite minerals. Sample 3271S 19 suspected to contain very minor amount of 20 serpentine, which may be chrysotile? Do you see 21 that? 22 A I do. 23 Q Is this the first time you learned that 24 the Colorado School of Mines was using the 25 centrifuge method and found tremolite asbestos and</p>

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<p>1 chrysotile in their testing?</p> <p>2 A I'm looking at this document and I don't 3 think this has anything to do with cosmetic testing 4 of talc. So the fact that they use a concentration 5 method is completely unrelated to cosmetic testing.</p> <p>6 And I know that if you look at the 7 table on page 8087 you can see at one where 41.6 8 percent weight of major magnesite -- it is just the 9 members here do not look like cosmetic talc. I 10 don't know what they were testing and why they were 11 using that method.</p> <p>12 Q But you are not an expert in the testing 13 methods, right?</p> <p>14 A I understand the general methodology, but 15 I'm not an -- I'm looking at this and telling you 16 this isn't cosmetic testing.</p> <p>17 Q Well, that wasn't the point of my 18 question. My question was whether this methodology 19 was recommended for the testing of asbestos by 20 Colorado School of Mines to Johnson and Johnson, and 21 that was the focus of my question.</p> <p>22 A The answer to your question is no, because 23 this has nothing to do with cosmetic testing.</p> <p>24 Q Well, let's go to 263. 263 is a report 25 from the Colorado School of Mines, and the title is,</p>	<p>1 method when you have to find something like a needle 2 in a haystack, correct?</p> <p>3 MR. SMITH: Objection.</p> <p>4 A They are not specifically saying this is a 5 a pre-concentration method, but they use a radiant 6 separation method and again, nothing in here that I 7 could see, although this is the first time I've seen 8 this, has anything about cosmetic testing and new 9 standards.</p> <p>10 Q You don't think this is about the 11 pre-concentration method?</p> <p>12 MR. SMITH: Objection.</p> <p>13 A The pre-concentration method, that's a 14 very specific method.</p> <p>15 Q Can you go to where it says objective?</p> <p>16 "The objective of the work was to develop a 17 procedure to screen for the talc for the presence of 18 chrysotile and tremolite and actinolite asbestos 19 minerals. Based on past experience with detecting 20 and identifying minerals when present at low levels 21 a concentration of the phases could be detected, was 22 considered essential to the success of any suggested 23 the procedure." Do you see that?</p> <p>24 A I do.</p> <p>25 MR. PLACITELLA: Let's take a break</p>
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<p>1 A Procedure to Examine Talc for the Presence of 2 Chrysotile and Tremolite, Actinolite Fibers, Johnson 3 and Johnson. Do you see that?</p> <p>4 A Yes.</p> <p>5 Q Go to the introduction. It says the 6 purpose of this document is to report the methods 7 used at Colorado School of Mines Institute for the 8 detection of chrysotile and/or tremolite actinolite 9 in samples predominantly composed of talc. Do you 10 see there?</p> <p>11 A Yes.</p> <p>12 Q It goes on to say, "As the impurity level 13 becomes very low, less than one percent, it is 14 necessary to examine increasingly larger amounts of 15 sample in order to detect the impurity. As a result 16 of requirement to detect the proverbial needle in a 17 haystack, we have evolved a procedure which 18 pre-concentrates the impurities prior to 19 examination." Do you see that?</p> <p>20 A Yes.</p> <p>21 Q And what they did is they again used a 22 centrifuge, correct?</p> <p>23 A Yes.</p> <p>24 Q And that was a method that was discussed 25 with Johnson and Johnson, the pre-concentration</p>	<p>1 now.</p> <p>2 THE VIDEOGRAPHER: The time is 3 approximately 2:11. We are going off the record. 4 (Recess taken)</p> <p>5</p> <p>6 THE VIDEOGRAPHER: We are back on the 7 record. The time is approximately 2:23 p.m.</p> <p>8 BY MR. PLACITELLA:</p> <p>9 Q Okay. Before you had referenced a couple 10 of times Dr. Pooley. Do you remember that?</p> <p>11 A Yes.</p> <p>12 Q You are aware, or can we agree, that Dr. 13 Pooley also recommended to Johnson and Johnson they 14 use of the pre-concentration method when using X-ray 15 diffraction?</p> <p>16 MR. SMITH: Objection.</p> <p>17 A No, I'm not aware of that.</p> <p>18 Q You are not aware of that?</p> <p>19 A No.</p> <p>20 Q 45 is a memo from May 16, 1973 on Johnson 21 and Johnson letterhead. Do you see that?</p> <p>22 A Yes.</p> <p>23 Q I assume you have seen this before?</p> <p>24 A I don't believe I have.</p> <p>25 Q Do you know who T.H. Shelley is?</p>

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<p>1 A No.</p> <p>2 Q Who is Dr. A.J. Goudie?</p> <p>3 A I don't know.</p> <p>4 Q Do you see where it says Dr. T. Shelley is going to go to England on May 25th?</p> <p>5 A Yes.</p> <p>6 Q That is where Dr. Pooley was, correct?</p> <p>7 A Yes.</p> <p>8 Q And it says that "England is considering method of pre-concentrating the asbestos so as to be able to analyze by x-ray." Do you recall see that?</p> <p>9 A Yes.</p> <p>10 Q It says, "They find no asbestos by doing this with Italian talc." Do you see that?</p> <p>11 A Yes.</p> <p>12 Q It says they find Pooley, Dr. Pooley, right?</p> <p>13 A Yes.</p> <p>14 Q Point zero five percent of a tremolite in Vermont, correct?</p> <p>15 A I see that, yes.</p> <p>16 Q Is this the first time you learned that Dr. Pooley used a pre-concentration method on Vermont talc and found tremolite?</p> <p>17 MR. SMITH: Objection.</p>	<p>1 in the research and development group.</p> <p>2 Q It says, "The British Toiletry Preparation Federation is in the process of drafting specifications on talc. These will involve density concentration techniques followed by x-ray analysis. Fred Pooley has developed the methods and checked the Italian talc for chrysotile and other asbestos contaminants. He found none. However, I'm concerned that our Vermont talc will from time to time show traces of tremolite." Do you see that?</p> <p>3 A I do.</p> <p>4 Q Have you ever seen this before?</p> <p>5 A No. Tremolite is not asbestos.</p> <p>6 Q My question is have you ever seen this document before?</p> <p>7 A Yes, I understand.</p> <p>8 Q Did you know before today that Dr. Pooley was involved in putting specifications together for Great Britain that recommended the concentration technique for testing?</p> <p>9 MR. SMITH: Objection.</p> <p>10 A I was not, and I have not seen the full recommendation on the specification.</p> <p>11 Q Today is the first time you learned that Dr. Pooley was working on the concentration method</p>
<p>1 A We know that there can be tremolite in association with talc. It doesn't say asbestos. So that's news.</p> <p>2 Pre-concentration method, is not recommending -- this in 1973. The J41 was developed and published in '76. How he used it and when he used it and why he used, it is not immediately apparent on this sheet.</p> <p>3 Q But it say he used a pre-concentration method and the .05 percent and when they were talking about -- let's just read it. "England is considering method of pre-concentrating the asbestos so as to be able to analyze by x-ray." Correct?</p> <p>4 A Yes.</p> <p>5 Q And they find no asbestos, in quotes, by doing this with the Italian talc. They find, that is Pooley, .05 percent of a tremolite type in Vermont." Correct?</p> <p>6 A Yes.</p> <p>7 Q Now, 46 is the follow up memo dated June 4, 1973. The re: is talc. Do you see that?</p> <p>8 A Yes.</p> <p>9 Q It states, it is to Dr. Robert F. Rolle. Do you know who that is?</p> <p>10 A He was in Johnson and Johnson, I believe,</p>	<p>1 in Great Britain and that was found in the Johnson and Johnson documents, the first time you knew that?</p> <p>2 MR. SMITH: Objection.</p> <p>3 A It is not the first time I knew that.</p> <p>4 Johnson and Johnson knew about the concentration method, was willing to discuss it with the FDA, so this is not -- I was not aware Pooley specifically had been working on it for the British Toiletry Association. That was your question. The answer was no.</p> <p>5 Q 47. Did you know that Dr. Pooley ran the concentration method on Vermont talc and found actinolite?</p> <p>6 MR. SMITH: Objection.</p> <p>7 A No.</p> <p>8 Q You have in front of you a June 6, 1973 memo on Johnson and Johnson stationery. I blew up the right portion. It says, it talks about the note from June 4th. Do you remember that, we just went through it?</p> <p>9 A Yes.</p> <p>10 Q It says, "Note the concentration techniques in the drafted specification for analysis of asbestos." Do you see that?</p> <p>11 A Yes.</p>

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<p>1 Q Then it goes on and says, "Shelley reports 2 that Pooley had found actinolite in our Vermont talc 3 by his concentrating technique." Do you see that? 4 A I do. Actinolite is not asbestos. 5 Q All I asked you was, do you see that. 6 A I do see it. 7 Q Okay. Is today the first time you learned 8 that Pooley found actinolite in the Vermont talc 9 using the concentration method? 10 MR. SMITH: Objection. 11 A Yes, but actinolite is not asbestos. 12 Q Ma'am, I'm asking you a simple question. 13 Is today the first time you learned that Pooley 14 found actinolite in Vermont talc using the 15 concentration method? 16 A Yes, and actinolite is not asbestos. 17 Q Ma'am, did I ask you whether your opinion 18 was whether it was asbestos or not? What can you 19 tell me? Tell me everything you know about 20 actinolite. 21 A We can go to the 1986 -- 22 Q No, Ma'am. I want to know everything you 23 know about actinolite. I don't want you to refer to 24 anything. Tell me everything you know about 25 actinolite.</p>	<p>1 mention actinolite, the complication I hear and how 2 you ask the question, that is asbestos, which it is 3 not. The clarification is important. 4 Q Ma'am, move to strike your testimony, with 5 all due respect. My question to you is tell me 6 everything that you, Dr. Nicholson, know from your 7 own mind, without reference to any documents about 8 actinolite. Tell me everything you know. 9 MR. SMITH: Objection. 10 A Extremely rare asbestos. 11 Q And based on what reference, besides the 12 1986 report that you are talking about? 13 A The 1986 report contains multiple 14 documents. One of them is a document called The 15 Misclassification of Asbestos. An excellent 16 reference that talks about all of the 1970s and of 17 the confusion and misrepresentation of various 18 finding by different microscopic techniques. It is 19 an excellent reference that clarifies many of the 20 things that you are pointing out today. 21 Q My question was what? 22 MR. SMITH: Objection. 23 Q What was my question? 24 A Repeat your question. 25 Q Do you have any idea what my question was?</p>
<p>1 MR. SMITH: Let me say that you can't 2 do that. 3 MR. PLACITELLA: Yes, I can do that, 4 and I will call the judge. 5 MR. SMITH: You can't -- 6 MR. PLACITELLA: I will call the 7 judge. 8 MR. SMITH: If you want to call the 9 judge, call the judge. You can't in the middle of 10 an answer just talk over the witness. 11 MR. PLACITELLA: I can when the 12 witness will not answer the question, Counsel. 13 MR. SMITH: The witness - 14 Q I'll withdraw the last question and the 15 ask the question again. Tell me everything you know 16 from your own knowledge without reference to any 17 documents, everything you know about actinolite? 18 A Because the specificity of words are 19 critical here, and very easy to confuse individuals, 20 whether they know this area or not, with language. 21 Using documents and referring to tables and decision 22 treatises, very nicely outlined in the 1986 FDA had 23 response to the citizens petition, is the right way 24 to review this subject, not shooting from hip. 25 So when you mention tremolite, you</p>	<p>1 A Well, sometimes I don't, but if you repeat 2 it I will. 3 Q Because you are going to wind up and say 4 whatever you are going to say regardless of my 5 question, right? 6 MR. SMITH: Objection. 7 A Incorrect. 8 Q Ma'am, can an honest and forthright 9 witness provide a simple answer to a simple 10 question? 11 A If it is asked clearly, yes, I can. 12 MR. SMITH: Excuse me. If we are 13 going to go down this trail, we are going to stop. 14 MR. PLACITELLA: You can stop at any 15 time you want. We will go to the judge. We will 16 let her read the transcript and she will decide 17 whether the witness is being responsive. If you 18 want to stop the deposition, stop the deposition, 19 otherwise I'm asking my questions. 20 MR. SMITH: You can't insult people. 21 MR. PLACITELLA: No one is being 22 insulted. 23 MR. SMITH: She is being insulted. 24 MR. PLACITELLA: No she isn't. 25 MR. SMITH: Yes, she is. You can't</p>

<p>1 do that.</p> <p>2 MR. PLACITELLA: No, she isn't.</p> <p>3 MR. SMITH: You can't do that. You</p> <p>4 can't cut witnesses off in the middle of an answer.</p> <p>5 You have got to stop that. If you want to keep it</p> <p>6 up, if you are saying you have a right to do that</p> <p>7 and you have a right to make insulting comments,</p> <p>8 then we will stop and we will give the transcript to</p> <p>9 the judge.</p> <p>10 MR. PLACITELLA: You know what, you</p> <p>11 stop the transcript any time you need to do it.</p> <p>12 MR. SMITH: I'm asking you to stop</p> <p>13 insulting the witness.</p> <p>14 MR. PLACITELLA: I'm not insulting</p> <p>15 the witness.</p> <p>16 MR. SMITH: Stop cutting her off in</p> <p>17 the middle of an answer. That's all I'm asking you</p> <p>18 to do. Ask her a question, she answers it and if</p> <p>19 you think she is not responsive, you move to strike.</p> <p>20 You don't insult her. You don't talk over her.</p> <p>21 MR. PLACITELLA: Are you done with</p> <p>22 your speech?</p> <p>23 MR. SMITH: But I'm asking you to</p> <p>24 just behave like that.</p> <p>25 MR. PLACITELLA: I'm asking you to</p>	<p>1 over her.</p> <p>2 Q Ma'am, do you agree with me that an honest</p> <p>3 and forthright witness can provide a simple answer</p> <p>4 to a simple question?</p> <p>5 MR. SMITH: Objection. I'm</p> <p>6 instructing you not to answer. That question is</p> <p>7 just to harass her and we are not doing that.</p> <p>8 Q Ma'am, did Dr. Pooley find actinolite</p> <p>9 using the pre-concentration method in Vermont talc?</p> <p>10 MR. SMITH: Objection.</p> <p>11 Q Yes or no?</p> <p>12 MR. SMITH: Objection.</p> <p>13 Q Yes or no? Can you not answer my question</p> <p>14 yes or no, Ma'am? Why don't we ask that question</p> <p>15 first. Answer my question, yes or no, did Dr. Pooley</p> <p>16 find actinolite using the pre-concentration method</p> <p>17 in Vermont talc? Can you answer that question, yes</p> <p>18 or no?</p> <p>19 MR. SMITH: Objection.</p> <p>20 A Yes, but he did not specify whether or not</p> <p>21 it was asbestosiform or not.</p> <p>22 Q I just asked you whether you could answer</p> <p>23 it yes or no. I didn't ask you anything more. Are</p> <p>24 you able to answer my question yes or no, whether</p> <p>25 Dr. Pooley found actinolite in Vermont talc using</p>
<p>1 just let me ask my questions, and if the witness</p> <p>2 will respond to the questions, we will get through</p> <p>3 the deposition.</p> <p>4 MR. SMITH: The witness is responding</p> <p>5 to the questions.</p> <p>6 Q Ma'am --</p> <p>7 MR. SMITH: If she wants to refer to</p> <p>8 a document, she is allowed to do that.</p> <p>9 MR. PLACITELLA: She can when you ask</p> <p>10 her questions. If I don't refer her to a document,</p> <p>11 then she can't.</p> <p>12 MR. SMITH: She's here as a corporate</p> <p>13 representative. She brought these documents to help</p> <p>14 refresh her recollection.</p> <p>15 MR. PLACITELLA: This is not form</p> <p>16 objection. You are way out of bounds here.</p> <p>17 MR. SMITH: No, you are out of</p> <p>18 bounds.</p> <p>19 MR. PLACITELLA: You are way out of</p> <p>20 bounds. I'm asking you not to do it.</p> <p>21 MR. SMITH: I'm happy to take this</p> <p>22 transcript to the judge, if that is what you want</p> <p>23 want to do.</p> <p>24 MR. PLACITELLA: Let's keep going.</p> <p>25 MR. SMITH: Not if you keep talking</p>	<p>1 the pre-concentration method?</p> <p>2 MR. SMITH: Objection.</p> <p>3 Q Can you answer that question yes or no?</p> <p>4 MR. SMITH: Objection.</p> <p>5 A I cannot answer it without misleading the</p> <p>6 jury.</p> <p>7 Q Did you rely upon Dartmouth College as one</p> <p>8 of the authorities for your submissions to the FDA</p> <p>9 on the issue of asbestos and Johnson's Baby Powder?</p> <p>10 MR. SMITH: Objection.</p> <p>11 A Yes.</p> <p>12 Q Are you aware that Dartmouth College used</p> <p>13 and recommended the concentration method when</p> <p>14 testing Johnson's talc?</p> <p>15 MR. SMITH: Objection.</p> <p>16 A I would have to go back and look at the</p> <p>17 exact documents to review their methods.</p> <p>18 Q The question is are you aware, as you sit</p> <p>19 here today, whether they did that or not?</p> <p>20 A I would have to go back and look at the</p> <p>21 documents to verify the testing methods.</p> <p>22 Q As you sit here today, you don't know</p> <p>23 whether Dartmouth College ever used the</p> <p>24 concentration method in assessing whether there was</p> <p>25 asbestos in Vermont talc?</p>

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<p>1 MR. SMITH: Objection.</p> <p>2 A I prefer to refer to the actual report to 3 be sure of what I'm answering, so I'll not answer 4 until I've had a chance to look at it.</p> <p>5 Q Find any document you want. Go ahead and 6 look.</p> <p>7 A They did use centrifugation. Just on a 8 quick glance I can't tell if all of their testing 9 used centrifugation or not.</p> <p>10 Q Did any of their testing find -- do you 11 know whether any of the Dartmouth College testing 12 ever found actinolite in the Vermont talc?</p> <p>13 A Based on the conclusion I see here, I 14 don't see actinolite mentioned, but I do see no 15 amphibole or garnet or asbestos impurities were 16 observed.</p> <p>17 Q In terms of the information that was 18 conveyed by Johnson and Johnson concerning the tests 19 that were done by Dartmouth College, the FDA was 20 never told one way or the other whether actinolite 21 or they found no actinolite. What is the answer?</p> <p>22 A I'm looking at the conclusions and I don't 23 see any reference to actinolite.</p> <p>24 Q Does it say no amphiboles were found, 25 regardless of whether they are asbestosiform?</p>	<p>1 using the concentration technique because it brings 2 amphiboles into a reasonable concentration range and 3 it says that is mandatory?</p> <p>4 A Yes, but it is important to look before 5 that. There's a whole discussion about how you can't 6 tell -- you could do grain counts, but you can't see 7 the specificity of the grain whether or not it is an 8 amphibole without concentrating.</p> <p>9 Q I'm fine with that. It says the reasons 10 stated, as you just stated, a concentration 11 technique is mandatory because it brings the 12 amphiboles into a reasonable concentration range for 13 optical and other methods of analysis, correct?</p> <p>14 A That is what it says.</p> <p>15 Q And if you go to page 6 where it says 16 results, and now they are testing for asbestosiform 17 minerals. Do you recall that? It says, "Two gram 18 samples of ore and ore spiked with actinolite 19 were separated and analyzed as described above." Do 20 you see that?</p> <p>21 A Yes.</p> <p>22 Q Then it talks about results are in table 23 2. It says table 3 shows concentrations of heavy 24 fractions, mostly carbonite and actinolite and talc 25 ore and talc product. Do you see that?</p>
<p>1 A Yes.</p> <p>2 Q I'll show you J and J 58. Did you provide 3 J and J 58 to the FDA at any point in time?</p> <p>4 A That document I was just looking is dated 5 June 28, 1971. I see numerous documents from March 6 of 1974, but I don't see that specific document.</p> <p>7 Q This document is entitled, from Dartmouth 8 College, Confidential, by the way, Analysis of Talc 9 Products and Ores for Asbestosiform Amphiboles. Do you 10 see that?</p> <p>11 A Yes.</p> <p>12 Q And Dartmouth College is one of the 13 experts that you relied upon in your submissions to 14 the FDA, correct?</p> <p>15 A At least in 1971, yes.</p> <p>16 Q And again in 1976?</p> <p>17 A Perhaps. I would have to go through this 18 and see.</p> <p>19 Q In this document dated March 1974, it 20 states, "The purpose of the study is to develop 21 methods for measuring the concentration of 22 asbestosiform amphiboles in fine grain talc products. 23 Do you see that?</p> <p>24 A Yes.</p> <p>25 Q You see on the second page it talks about</p>	<p>1 A Yes.</p> <p>2 Q So you see that here they are actually 3 using the concentration method and recommending it 4 in order to determine whether amphiboles are in the 5 Vermont product, correct?</p> <p>6 MR. SMITH: Objection.</p> <p>7 A What I've seen, and again I'm not an 8 expert in all the methodology from just what you 9 have shown me, is that they needed it for this 10 specific methodology.</p> <p>11 I don't know that you can universally 12 say you have to use the concentration method with 13 this optical microscopic technique. That's what 14 they are saying.</p> <p>15 Q What they are saying to Johnson and 16 Johnson is that it is mandatory. Isn't that their 17 words?</p> <p>18 A You can't take that out of context though. 19 It is mandatory when using the optical microscopic 20 technique they are using, not for every method 21 available.</p> <p>22 Q It talks about on page 7 when they use 23 the concentration method, they found ore samples 24 contain 2300 parts per million actinolite and the 25 talc product contains 170 parts per million</p>

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<p>1 actinolite. Actinolite is the dominant fiber form 2 amphibole in the ore and talc product provided by 3 Windsor Minerals. Small amounts of anthophyllite 4 might be present. 5 That is what they wrote, correct? 6 A I see that. I'll say that that does not 7 mean it is asbestos. 8 Q Ma'am, I'm just asking if that's what they 9 wrote. 10 A Yes, I understand. I don't want the 11 answer to be misleading. 12 Q When up told the FDA that there was no 13 amphibole of any sort ever found in a Johnson and 14 Johnson talc product, you did not include this 15 report, correct? 16 A I didn't see the report here, so I can't 17 say that we had sent it for sure. And I don't know 18 what the sample was that they tested, so I would 19 have to go back and verify that to answer your 20 question definitively. 21 Q You never even saw this report until as 22 you are sitting here right now, right? 23 A Well, I've looked at a lot of reports and 24 they are kind of technical. So you have to really 25 look at them very carefully. I don't recall this</p>	<p>1 concentrate. The method is straightforward and 2 rapid requiring about 20 minutes of operator time 3 and about one hour overall. If removal of 4 carbonates is desired, these times may become 30 5 minutes to two hours respectively." Do you have see 6 that? 7 A Yes. 8 Q To be fair to you, you had never seen this 9 before today, correct? 10 A No, but I can -- I see it now and I've 11 read through it. 12 Q We are going to be back here again, so 13 I'll ask you more questions when you have some 14 time to digest. 15 A I don't need time. I can see what it 16 means. 17 Q Am I correct that internally, as a follow 18 up to this, Johnson and Johnson actually 19 acknowledged that the concentration method was the 20 best method? 21 MR. SMITH: Objection. 22 A I doubt that because this basically says 23 it is a very difficult method and hard to quantify. 24 It sounds like it is extremely difficult to 25 execute.</p>
<p>1 one specifically, but again, I have not dug through 2 again to see if this matches up to the one I have. 3 Q And it is not in that book in front of you 4 of test results given to the FDA, correct? 5 A I didn't see it there. 6 Q 352. Are you aware that after Johnson and 7 Johnson got this report they actually discussed it 8 internally and verified the method? 9 A No, I was not aware of. 10 Q You have in front you 3-11-74, March 11, 11 1974 memo on Johnson and Johnson letterhead. The 12 subject, method of concentration of asbestos in 13 talc. Do you see that? 14 A Yes. 15 Q It talks about the procedure used by Dr. 16 Reynolds from Dartmouth, correct? 17 A Yes. 18 Q What you write internally is, "The 19 procedure for heavy fibers actinolite and tremolite 20 permit the detection of asbestos at original 21 concentration as low as .02 percent by weight while 22 the existing procedures, step scanning, X-ray 23 diffraction, are effective to .02 percent. The 24 dispersion staining technique of optical microscopy 25 was employed to detect tremolite fibers in the</p>	<p>1 Q Johnson and Johnson, after having 2 discussions about the concentration method with Dr. 3 Pooley, Dartmouth University and Colorado School of 4 Mines, after having all those discussions, fought 5 against the FDA using that method, didn't 6 they? 7 MR. SMITH: Objection. 8 A I don't think we fought against anybody. 9 Q Did you actually conclude, Johnson and 10 Johnson, that adoption of a pre-concentration method 11 by the FDA would be disturbing and troublesome for 12 Johnson and Johnson? 13 A Well, based on the documents you just gave 14 me, I would not be surprised if that was a 15 recommendation, but it sounds like it is very 16 difficult to do, hard to repeat, technically 17 intense, so probably not the kind of thing that most 18 individuals could execute. 19 Q Ma'am, I'm asking you whether internally 20 you, Johnson and Johnson, determined that you were 21 going to oppose adopting the pre-concentration 22 method by the FDA because it was disturbing and 23 troublesome to Johnson and Johnson? 24 MR. SMITH: Objection. 25 A I don't think it would be disturbing and</p>

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<p>1 troublesome to Johnson and Johnson. As I just said, 2 it sounds like it is a very difficult method to 3 execute.</p> <p>4 Q 471 is a memo from Mr. Ashton dated 5 November 24, 1976. Do you see that? Have you ever 6 seen this document before?</p> <p>7 A I don't believe I have.</p> <p>8 Q Here it says, Mr. Ashton, by the way, was 9 known inside of Johnson and Johnson as Mr. Talc, 10 correct?</p> <p>11 A I don't know.</p> <p>12 Q Do you see where it says Mr. Ashton writes 13 to George Lee, "Attached is a copy of a disturbing 14 proposal request which the FDA has currently made 15 available to qualified bidders. The scope of the 16 work is the separation of asbestos and food, drugs 17 and talc for identification and determination." Do 18 you see that?</p> <p>19 A Yes.</p> <p>20 Q 369. And Johnson and Johnson, actually 21 after hearing recommendations from their own 22 experts, came to the conclusion that using the 23 concentration method was not in the interest of 24 Johnson and Johnson, correct?</p> <p>25 MR. SMITH: Objection.</p>	<p>1 would not be in the worldwide company interest to do 2 this, correct?</p> <p>3 MR. SMITH: Objection.</p> <p>4 A Yes.</p> <p>5 Q And what you ultimately determined was 6 that you wanted to avoid using this technique at all 7 costs and keep it quiet, right?</p> <p>8 MR. SMITH: Objection.</p> <p>9 A No.</p> <p>10 Q 353. I'm going to show you what's been 11 marked February 28, 1975, on Johnson and Johnson 12 letterhead. Subject, review of CTFA methodology for 13 the detection of asbestos in talc as well as 14 comments on PPF methodology. Do you see that?</p> <p>15 A Yes.</p> <p>16 Q It goes through here the methodology that 17 Johnson and Johnson wants adopted, correct?</p> <p>18 A This looks like a proposed methodology.</p> <p>19 Q And how Johnson and Johnson concludes the 20 memo is, "We really want to exclude concentration 21 techniques in any proposed analytical procedure and 22 are really looking at this method very quietly. So 23 that we will be well informed and up to date with 24 this technology. We want to avoid promotion of 25 this approach." Did you ever see that before?</p>
<p>1 A Are you looking at this document that you 2 just gave me?</p> <p>3 Q No, I'm asking a different question.</p> <p>4 A Can you please repeat that?</p> <p>5 Q Yes, Ma'am. After getting advice from 6 your experts about the viability of the 7 concentration method and its usefulness. Johnson 8 and Johnson came to the conclusion that the adoption 9 would not be in the interest of Johnson and Johnson 10 worldwide, correct?</p> <p>11 MR. SMITH: Objection.</p> <p>12 A I don't know what you are looking at, but 13 I would accept that's true because of the other 14 documents you have gave me that is a technically 15 difficult method to execute.</p> <p>16 Q You have in front of you 369?</p> <p>17 A Yes.</p> <p>18 Q This is a memo from 1975, again, on 19 Johnson and Johnson letterhead?</p> <p>20 A Yes.</p> <p>21 Q And it talks about Dr. Pooley again and 22 his recommendations? Correct?</p> <p>23 A Yes, I see that.</p> <p>24 Q And what you say is we deliberately have 25 not included a concentration technique as we felt it</p>	<p>1 MR. SMITH: Objection.</p> <p>2 A I have not, but I've seen in documents 3 noting that discussions where Johnson and Johnson 4 has said we will be happy to discuss this method.</p> <p>5 Q This document says you want to avoid the 6 promotion of this approach, doesn't it, when it 7 talks about your methodologies?</p> <p>8 MR. SMITH: Objection.</p> <p>9 Q That's what it says.</p> <p>10 Q That's what it says, but it doesn't mean 11 we were trying to suppress it. It means we weren't 12 promoting it.</p> <p>13 Q You didn't want it adopted.</p> <p>14 A You showed me documents just a minute ago 15 that showed it was technically intense and difficult 16 to execute.</p> <p>17 Q You say you wanted to keep this very 18 quiet. That is what the document says, right?</p> <p>19 MR. SMITH: Objection.</p> <p>20 A So, my experience dealing with the FDA, 21 especially when there are multiple other companies, 22 if you raise an issue, everybody starts talking 23 about it and it can be real conversations.</p> <p>24 We did say very explicitly to the 25 FDA, if you would like to discuss it we would be</p>

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<p>1 happy to talk to you about it. We were not 2 oppressing it, but we didn't think it was a good 3 methodology, and you just showed me a document that 4 says it was technically difficult to perform. So it 5 wouldn't be in a standard methodology that others 6 perhaps could not get and repeat consistently.</p> <p>7 Q But your experts did it multiple times 8 over, didn't they?</p> <p>9 MR. SMITH: Objection.</p> <p>10 A They are experts.</p> <p>11 Q That is the point, Ma'am, isn't it?</p> <p>12 Experts in the testing could use the methodology and 13 in fact your experts did and were successful in 14 using it, true?</p> <p>15 MR. SMITH: Objection.</p> <p>16 A In the discussion of the developments of 17 methodologies, correct.</p> <p>18 Q But even though your expert used the 19 methodology and recommended it, it was your position 20 that you wanted to look at it very quietly and avoid 21 promotion, correct?</p> <p>22 MR. SMITH: Objection.</p> <p>23 Q That was your position, Johnson and 24 Johnson's position?</p> <p>25 MR. SMITH: Objection.</p>	<p>1 MR. SMITH: Objection.</p> <p>2 A I'll have to look at what you are 3 referring to.</p> <p>4 Q Are you aware of that as you sit here 5 today?</p> <p>6 A No, I'm not. Not in production material, 7 talcum powder.</p> <p>8 Q So you are not, as you sit here, just so 9 we are clear, you are not aware of any test done for 10 Johnson and Johnson on Johnson's Baby Powder using 11 the concentration technique that found asbestos?</p> <p>12 A No.</p> <p>13 Q If you are not aware of it, you certainly 14 didn't provide it to the FDA. Is that fair?</p> <p>15 A Yes.</p> <p>16 Q I want to focus a little bit, at least get 17 some background on the Lewin report and the 18 exchanges with the FDA by Johnson and Johnson on the 19 Lewin report, okay?</p> <p>20 A Yes.</p> <p>21 Q Hopefully we won't get too much 22 controversy over this.</p> <p>23 Is it your understanding that Dr. 24 Lewin tested a series of talc based products in the 25 early 1970s for the FDA? You are aware of that?</p>
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<p>1 A So I'll say again. I'm reading this and I 2 see this, and based on the other information that we 3 have seen, it makes sense to me we would not want it 4 to become a prominent part of the discussion 5 because it is a technically difficult method to 6 execute, and when people who are not experts try to 7 reproduce it, even people in Johnson and Johnson's 8 labs, they were getting variable results. You 9 showed me that document a couple minutes ago.</p> <p>10 MR. PLACITELLA: This is a good time 11 to take a break.</p> <p>12 THE VIDEOGRAPHER: The time is 13 approximately 3:00 p.m. and we are going off the 14 record.</p> <p>15 (Recess taken)</p> <p>16 THE VIDEOGRAPHER: The time is 17 approximately 3:13 p.m. and we are back on the 18 record.</p> <p>19 BY MR. PLACITELLA:</p> <p>20 Q I assume that you are aware that Johnson 21 and Johnson hired experts to test Johnson's Baby 22 Powder that used the concentration technique and 23 found asbestos?</p>	<p>1 A Yes.</p> <p>2 Q And you are aware that Dr. Lewin, 3 according to his analysis, found asbestos in some of 4 those products?</p> <p>5 A Thought he found asbestos in some of those 6 products, yes.</p> <p>7 Q Do you know if he issued a report -- let's 8 make sure we are on the same page, August 3, 1972. 9 You have seen that, correct?</p> <p>10 A Yes.</p> <p>11 Q I'll put it on the screen. August 3, 12 1972, a letter from Lewin to the FDA enclosing his 13 final analytical results, correct?</p> <p>14 A Yes.</p> <p>15 Q Is this report one of the results he had 16 was that in this analysis he found chrysotile 17 asbestos in Johnson's Baby Powder, correct?</p> <p>18 A He thought he did. That's what he said, 19 later refuted.</p> <p>20 Q Ma'am, I'm just asking you. I didn't what 21 ask you what he thought. I said in this analysis as 22 reported in this particular document, he found 23 asbestos in the Johnson's Baby Powder, correct?</p> <p>24 MR. SMITH: Objection. Let me ask, 25 were you in the middle of your answer?</p>

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<p>1 A I'm okay.</p> <p>2 Q I'm not asking you whether he changed 3 later on. We will get to that. I'm giving you every 4 opportunity.</p> <p>5 I'm saying in this report, what he 6 reported in his analysis was finding asbestos in the 7 Johnson and Johnson product, correct?</p> <p>8 A He thinks he found asbestos. So that is 9 what he said, but his methods were not sufficient to 10 say that.</p> <p>11 Q In this report does it say anything about 12 his methods not being efficient to say that?</p> <p>13 A He didn't know that at the time.</p> <p>14 Q All I'm asking you, please, is in this 15 report what he reported in his analysis was that he 16 found asbestos in Johnson Baby Powder, correct?</p> <p>17 A He reported he thought he found asbestos. 18 That's correct.</p> <p>19 Q And after that report came down, Johnson 20 and Johnson had conversations with the FDA about the 21 report, correct?</p> <p>22 A Yes.</p> <p>23 Q And in those conversations the FDA 24 promised Johnson and Johnson not to release the 25 Lewin Report publically until Johnson and Johnson</p>	<p>1 Q Right about that time Johnson and Johnson 2 found out that the FDA had hired a second contractor to 3 test the talc products, that being Sperry-Rand, correct?</p> <p>4 A Where would I see that in this document?</p> <p>5 Q I'm asking whether you know that.</p> <p>6 A I know that multiple people tested the talc.</p> <p>7 Sperry-Rand, I don't remember the name specifically.</p> <p>8 Q I'm talking about who the FDA hired. Do 9 you know that they hired Sperry-Rand to test the 10 Johnson and Johnson talc?</p> <p>11 A I know they hired an outside group to do 12 that. I don't remember the exact name, if it is 13 Sperry-Rand or somebody else.</p> <p>14 Q Have you seen any of the reports by 15 Sperry-Rand?</p> <p>16 A I've seen the reports of the FDA testing 17 or their contracted testing of the Lewin samples, if 18 that is what you are referring to.</p> <p>19 Q Sperry-Rand is -- I'm sorry. 29 is an 20 August 24, 1972 memo entitled Talc Asbestos Shower 21 to Shower Talc. Have you seen this before?</p> <p>22 A I don't recall this specific document.</p> <p>23 Q And apparently, and this document was not 24 provided at any time to the FDA, correct?</p> <p>25 A Not that I recall specifically.</p>
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<p>1 had a chance to review it, fair?</p> <p>2 A Yes, that's correct.</p> <p>3 Q 347 in this report, in this particular 4 letter dated August 29, 1972, Johnson and Johnson 5 writes on the subject of talc in asbestos in Shower 6 to Shower brand body powder, correct?</p> <p>7 A Yes.</p> <p>8 Q What is reported is that the author spoke 9 with the FDA on two different occasions, correct?</p> <p>10 A Yes.</p> <p>11 Q And brought them up to speed on the 12 findings of Professor Pooley, correct?</p> <p>13 A Yes.</p> <p>14 Q That no chrysotile was found in the 15 Italian talc, correct?</p> <p>16 A Yes.</p> <p>17 Q Not reflected anywhere in here is the 18 findings of Professor Pooley finding actinolite in 19 the Vermont talc, correct?</p> <p>20 A That is correct.</p> <p>21 Q It goes on to say that Dr. Schaffner at the 22 FDA agreed not to release the Lewin Report until 23 after Johnson and Johnson had a chance to go over 24 it, fair?</p> <p>25 A Yes.</p>	<p>1 Q What this does, and we will go through it 2 slowly, since you haven't seen it. It says, "Dr. 3 Weisler, Director, Division of Cosmetics, FDA, 4 called us this afternoon to report they had 5 submitted a sample of Shower to Shower previously 6 examined by Dr. Lewin to the Sperry-Rand scanning 7 electronic microscopy this afternoon." Do you see 8 that?</p> <p>9 A Yes.</p> <p>10 Q Does that refresh your memory?</p> <p>11 A Yes. I'm familiar with another master 12 table that was not Sperry-Rand of retesting for the 13 Lewin samples. That's why it took me a minute.</p> <p>14 Q Are you aware of this and did you 15 investigate this conversation that Johnson and 16 Johnson had with the Director at the FDA concerning 17 the Sperry-Rand testing?</p> <p>18 A No, because I was looking at this January 19 7, 1976 Lewin retest document.</p> <p>20 Q We are going to get there. I promise. 21 Right now I'm focusing on the conversations that 22 Johnson and Johnson had with the FDA concerning the 23 Shower to Shower Sperry-Rand testing. Are you with 24 me?</p> <p>25 A Yes.</p>

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<p>1 Q It states, "Report from Sperry-Rand was 2 that asbestos fibers could be detected in the 3 sample. Dr. Weisler said that he has in front of 4 him photographs of six fields at 12,000 X 5 magnification showing fibers with length to width 6 ratios of 10 to 1, to 50 to 1. One of them 7 appearing on the top talc plate." Do you see that? 8 A Yes. 9 Q It goes on to say that, "Johnson and 10 Johnson asked the FDA if Sperry-Rand handles 11 minerals, and the response was that they do a lot of 12 work with chrysotile." Correct? 13 A Yes. 14 Q The FDA further told Johnson and Johnson 15 that they believed that, "the man who did the work is 16 conservative and he would not have reported 17 chrysotile unless he was sure." Correct? 18 A Yes. 19 Q And Johnson and Johnson asked, "if he has 20 assured himself, that is the FDA, that the fibers 21 were not tremolite, which could be present in trace 22 amounts." And the response was, "He said the fibers 23 are characteristic of chrysotile and not tremolite." 24 Do you see that? 25 A Yes.</p>	<p>1 surprised again, because chrysotile would not be 2 found in talc. 3 Q Did I ask you that Ma'am, whether you were 4 surprised or not? Do you really want me to have a 5 judge read this and make a determination of whether 6 you are truly being responsive? 7 MR. SMITH: Objection. 8 Q Are we really going to do this? 9 MR. SMITH: Objection. Just ignore 10 those comments. 11 Q Are we really going to do this? 12 MR. SMITH: Please don't do that. 13 Please don't do that. It is not helpful. 14 Q Do you know anything about this conversation? 15 A Not until you showed it to me today. 16 Q It goes on to say that, "That information 17 is completely at variance with Johnson and Johnson's 18 information," correct? 19 A Specifically from McCrone, and we have a 20 letter here that says that 1971 through '76 McCrone 21 never found any asbestos in our talc material, so 22 yes, I'm well aware of that. 23 Q As you stand here as the witness for 24 Johnson and Johnson, let's be very clear. Are you 25 telling this jury that from 1971 to 1976 McCrone</p>
<p>1 Q Do you have any knowledge of this conversation? 2 A I don't, but I'm not concerned because 3 chrysotile is an industrial asbestos fiber and not 4 found in talc material, so this speaks to me of 5 laboratory contamination. 6 Q Ma'am there's nothing in here about 7 laboratory contamination. I'm just asking if you 8 know anything about the conversation. 9 A I know what you are asking me, and I just 10 want to make sure you understand that chrysotile 11 does not occur in talc materials unless it is an 12 environmental contaminant. 13 Q Ma'am, did I ask you that question? 14 A No. But I thought it might be helpful to 15 your understanding. 16 Q I'm not asking you to help me with my 17 understanding. I'm asking you to answer questions 18 that are posed. 19 My question is, do you have any 20 information in your investigation about this 21 conversation that Johnson and Johnson had with the 22 FDA where the FDA related their contractor 23 found chrysotile asbestos in the Johnson and Johnson 24 products? That's all I'm asking. 25 A Not specifically, no, but I'm not</p>	<p>1 never found asbestos in any Johnson and Johnson talc 2 material? Is that what you are saying? 3 A Our production material, tested by McCrone, 4 did not have asbestos in it from 1971 to 1976. 5 Q I'm asking you Ma'am, are you telling this 6 jury, because it is important, that no test by 7 McCrone ever found asbestos from 1971 to 1976 in 8 Johnson and Johnson talc? Is that what you are saying? 9 MR. SMITH: Objection. 10 A There were two instances that were 11 referred to in that letter I mentioned that was 12 written in 1976 referring to 1971 to 1976. They 13 said in the last five years, and we have the letter 14 here that we can look at, and they did mention, I 15 believe, or maybe it was in a later letter, that 16 they had two instances of asbestos contamination 17 from external sources and they were able to verify 18 where those asbestos materials came from. 19 Q What was my question? 20 A You asked me if they never found any 21 asbestos, and there were some contaminant events. 22 I'm answering your question. 23 Q Your answer to the question is but for two 24 contamination events, McCrone never found any 25 evidence of asbestos when testing Johnson and</p>

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<p>1 Johnson talc. Is that what you are saying?</p> <p>2 A That is my understanding of talc cosmetic powders.</p> <p>3 Q Did McCrone ever find asbestos when testing</p> <p>4 the talc mine sources that were used for Johnson</p> <p>5 and Johnson cosmetic talc products?</p> <p>6 MR. SMITH: Objection.</p> <p>7 A We would have to look at those reports.</p> <p>8 There are extensive surveys of the shafts that are</p> <p>9 used for cosmetic talc and they are complex</p> <p>10 documents that need to be looked at specifically to</p> <p>11 go through that.</p> <p>12 Q Ma'am, I'm just asking whether you know,</p> <p>13 as the representative of Johnson and Johnson,</p> <p>14 whether McCrone ever tested talc that was used in</p> <p>15 the Johnson and Johnson cosmetic talc products and</p> <p>16 found asbestos. That is my question.</p> <p>17 MR. SMITH: Objection.</p> <p>18 A I think you have changed the question.</p> <p>19 Q That is my question. Can you answer that</p> <p>20 question?</p> <p>21 A Did McCrone ever find asbestos in cosmetic</p> <p>22 talc products. That was your question.</p> <p>23 Q No, Ma'am. My question was, did McCrone</p> <p>24 ever find asbestos in the talc that was used to</p> <p>25 manufacture -- I'll make it easier. I'll start over.</p>	<p>1 A I recall, and I have read documents,</p> <p>2 minutes from the meeting where the FDA came to</p> <p>3 Johnson and Johnson to discuss testing. I know</p> <p>4 there were other individuals there. I don't recall</p> <p>5 any conditions of who was going to speak, but I'm</p> <p>6 not surprised that there was a very specific agenda</p> <p>7 agreed to, if that's what you are referring to.</p> <p>8 Q Well, you know that before you had the</p> <p>9 meeting with other industry members, you had a</p> <p>10 private meeting with the FDA about the Lewin</p> <p>11 results, true?</p> <p>12 A Yes, and that is not unusual, if we are</p> <p>13 talking about our specific products.</p> <p>14 Q You, Johnson and Johnson, actually got an</p> <p>15 advanced copy of the Lewin Report before it was ever</p> <p>16 made available to any consumers or doctors or</p> <p>17 members of Congress, correct?</p> <p>18 MR. SMITH: Objection.</p> <p>19 A Yes.</p> <p>20 Q When you met with the FDA, you assured the</p> <p>21 FDA that you gave them your entire background file</p> <p>22 on asbestos talc testing as it related to your</p> <p>23 cosmetic talc products, correct?</p> <p>24 A I don't know that specifically. I would</p> <p>25 have to go back and look at those documents to see</p>
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<p>1 Did McCrone ever find asbestos in</p> <p>2 any form in the source of the talc that was used for</p> <p>3 Johnson's cosmetic talc products?</p> <p>4 A They never found asbestos in the material</p> <p>5 that was used to make Johnson's Baby Powder.</p> <p>6 Q And that is what you told the FDA, you,</p> <p>7 Johnson and Johnson, correct?</p> <p>8 A That's correct.</p> <p>9 Q And you have actually met with the FDA and</p> <p>10 told them, in reviewing the Lewin reports, that</p> <p>11 there was never even a trace of chrysotile asbestos</p> <p>12 found in any Johnson and Johnson cosmetic talc</p> <p>13 product, true?</p> <p>14 A True.</p> <p>15 MR. SMITH: Objection.</p> <p>16 Q At some point you sat down with the FDA</p> <p>17 and actually discussed that issue about the Lewin</p> <p>18 results, correct?</p> <p>19 A Yes.</p> <p>20 Q And what you arranged at Johnson and</p> <p>21 Johnson was a private meeting with the FDA that you</p> <p>22 would have with the officials at the FDA and then</p> <p>23 you could agree with the FDA who would be allowed to</p> <p>24 speak at the meeting involving people other than</p> <p>25 Johnson and Johnson, correct?</p>	<p>1 what exactly was given.</p> <p>2 Q Exhibit 40 is a December 13, 1972 memo</p> <p>3 that discusses the meeting that you had with the FDA</p> <p>4 on November 1, 1972, correct?</p> <p>5 A Yes.</p> <p>6 Q What you indicated is that you pointed out</p> <p>7 and provided information and ordered your complete</p> <p>8 background files concerning talc and asbestos, correct?</p> <p>9 A Yes.</p> <p>10 Q Did you actually provide the FDA with your</p> <p>11 complete background files?</p> <p>12 A In November 29, 1972, we sent a number of</p> <p>13 documents. These are reports of retained samples</p> <p>14 from two lots that were examined by multiple</p> <p>15 different organizations.</p> <p>16 Q At that point in time did you provide the</p> <p>17 FDA with all of the asbestos testing evidence you</p> <p>18 had related to your cosmetic talc products?</p> <p>19 MR. SMITH: Objection.</p> <p>20 A What I show here is we sent a number of</p> <p>21 different reports, testing of certainly lots.</p> <p>22 That's what I show that we sent to the FDA.</p> <p>23 Q That wasn't my question.</p> <p>24 MR. PLACITELLA: Are you able to read</p> <p>25 my question back.</p>

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<p>1 (The above question is read.) 2 MR. SMITH: Note my objection. 3 A So, I as I said, November 29, 1972, as 4 pointed out in this December 13th memo, I pointed out 5 providing information, offered our complete 6 background files. Not all the tests have 7 backgrounds files, to the administration prior to 8 public disclosure, et cetera, and I have that here. 9 It was provided to you in binder P-3. 10 Q Can you identify the letter that you are 11 referring to by date? 12 A Tab C, November 29, 1972 letter. 13 Q So on November 29, 1972, it is your 14 testimony here under oath that Johnson and Johnson 15 provided the FDA with all the testing evidence that 16 it had related to whether there was asbestos in 17 Johnson and Johnson cosmetic talc products, correct? 18 MR. SMITH: Objection. 19 A As I corrected you before, not all of the 20 testing information, complete background files. 21 This is one, two, three, four, five different sets 22 of documents around testing, and it refers to two 23 specific lots. 24 So you are saying all of the 25 extensive testing. I don't know if there's other</p>	<p>1 A I don't know. 2 Q And ultimately was a letter generated from 3 the FDA summarizing the information and a product of 4 what your discussions were and the input you provided? 5 A From FDA? 6 Q Yes, Ma'am. 7 A There was a letter from the FDA. 8 Q I'll show you what's been marked Exhibit 9 50. 50 is a July 31, 1973 memo, a letter from the 10 FDA talking about a summary and comments on 11 Professor Lewin's analytical results for asbestos, 12 correct? 13 A Yes. 14 Q You have seen that before? 15 A Yes. 16 Q That was part and parcel of the product of 17 the discussion and submissions that you had given to 18 the FDA on this subject, true? 19 A This is from the FDA, not from us. 20 Q No, we are talking this was the product 21 of, in part, of the discussions you had with the 22 FDA and the submissions you gave them. 23 A That's correct. 24 Q And in fact, the FDA notes on the second 25 page of the document that you dispute the findings</p>
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<p>1 testing that would fall under the umbrella you are 2 putting up. This is what was sent to the FDA and it 3 is comprehensive related to these two lots. 4 Q So everything you sent to the FDA is in 5 that binder? 6 A That is correct. 7 Q In your meeting you express your concern 8 to the FDA about the Lewin results, correct? 9 A Yes. 10 Q And you actually got the FDA official to 11 agree not to release the Lewin results. I think he 12 actually said, "Over my dead body will I release 13 them." Is that right? 14 MR. SMITH: Objection. 15 A Yes, he did say that. 16 Q At that point in time was your former 17 executive working at the FDA? 18 A I'm sorry? 19 Q Your former executive who worked on talc, 20 was he working at the FDA at that point in 21 time? 22 MR. SMITH: Objection. 23 A I don't know which executive you are 24 referring to. 25 Q Dr. Eiermann. Yes or no?</p>	<p>1 of Lewin using your own analysis and that no 2 chrysotile was found, right? 3 A Yes. 4 Q 38. So we are all on the same page, I 5 think this is what you referenced. I'm going to 6 give you what's been marked J and J 38, and J and J 7 38 is your letter to the FDA enclosing various 8 expert testing results, correct? 9 A Yes. 10 Q And those included reports from McCrone, 11 correct? 12 A Yes. 13 Q They included reports from Dr. Brown at 14 Princeton? 15 A Yes. 16 Q Correct? They included reports from the 17 Colorado School of Mines? 18 A Yes. 19 Q Your notes that have been marked as P-2, I 20 don't really see anything in your notes related to, 21 I'll call it the Lewin related testing, correct? 22 A All in the binders here. 23 Q I'm asking whether it is in your notes. 24 A Not that I remember. Something about the 25 1971 EPA State of New York symposia that it leads to</p>

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<p>1 Lewin testing.</p> <p>2 Q What do you know about that?</p> <p>3 A Just what I wrote down.</p> <p>4 Q That's all you know?</p> <p>5 A No. There was a 1971 meeting and the 6 issue of asbestos testing and talc came up. Dr. 7 Lewin was hired by FDA to do some testing and that 8 led to the test results we have been discussing.</p> <p>9 Q I'm looking at your notes, on the second 10 page it talks about, it says on page 2, "Reuters 11 article lays out the theme." What does that mean?</p> <p>12 A There was a recent Reuters article written 13 about talc, Johnson and Johnson and talcum powder, 14 and some of the legal activities.</p> <p>15 Q That's something you read in preparation 16 for today's deposition?</p> <p>17 A I did. I reread it.</p> <p>18 Q And then it says pivot back to. What do 19 you mean by pivot back to?</p> <p>20 A I would have to look at the notes there. 21 This refers to the fact that when you are talking 22 about testing, you could easily pick out one 23 document and present that as if it told the whole 24 story of what people understood about asbestos 25 testing and talc, and that is not correct. That</p>	<p>1 and the response is pivot back to. We are not 2 playing games with language.</p> <p>3 MR. SMITH: Objection.</p> <p>4 A We are talking about asbestos. That's 5 what I mean.</p> <p>6 Q It says, "No documentation validated 7 positive test for asbestos. Then that material was 8 used. That's why we use standards." That is your 9 response to the Reuters article?</p> <p>10 A As we have done here today, you can pick 11 out a little note here and a note there and imply 12 that reflects that Johnson and Johnson products are 13 contaminated with asbestos.</p> <p>14 There's no evidence to show that we 15 ever released product to market that contained 16 asbestos. And that's just a fact, and the McCrone 17 letters in 1986 and 1976 refer to many, many years 18 of negative testing of production material of 19 Johnson's Baby Powder and Shower to Shower.</p> <p>20 Q I'm just trying to understand your notes.</p> <p>21 A I think they are good notes. Thanks for 22 bringing it up.</p> <p>23 Q I was curious why, in preparation for 24 today's deposition, you were talking about pivoting 25 from the Reuters article.</p>
<p>1 there's years of discussion and scientific debate 2 about what is the appropriate testing for talc. And 3 what is the right methodology, and Lewin really 4 opened that up. And you see that laid out over a 5 number of years leading to the J41.</p> <p>6 And so pivot back to a framework that 7 lays out the context in which these documents lie so 8 that nobody is misled to something that may not be true.</p> <p>9 Q I want to make sure we are -- you say 10 Reuters articles lays out the theme. Pivot back to.</p> <p>11 Then you say, "We are not playing 12 games with language. Go to McCrone letters." What 13 does that mean?</p> <p>14 A That means when you say Tremolite, that 15 does not mean asbestos. When you say actinolite, 16 that does not mean asbestos. You say amphibole, 17 that does not mean asbestos.</p> <p>18 It is very easy to confuse individuals 19 by using a lot of geologic, nomenclature, nameology, 20 and so just in plain speak, asbestos is what asbestos 21 is, and you have to understand that. It is a disease 22 causing febrile formations that are of concern that 23 we have to make sure are not in our products.</p> <p>24 That's the bottom line.</p> <p>25 Q But we are going to the Reuters article</p>	<p>1 Did you think I was going to ask you 2 about the Reuters article?</p> <p>3 A No, but I think the Reuters article picked 4 up on some flashy facts and to make a story, and 5 those facts were taken out of context of the 6 framework of what's been going on in the last 50 7 years around understanding asbestos testing and 8 talcum powder.</p> <p>9 Q Were there discussions inside of Johnson 10 and Johnson that you were a party to that were in 11 response to the Reuters article?</p> <p>12 A Many people have asked me about talc 13 safety in light of the Reuters article.</p> <p>14 Q When you say many people, I'm talking 15 about inside of Johnson and Johnson.</p> <p>16 A Yes.</p> <p>17 Q Did you have a conversation with the 18 CEO about it?</p> <p>19 A No.</p> <p>20 Q Who did you speak to inside of Johnson and 21 Johnson about the response to the Reuters article?</p> <p>22 A Well, many people in the company know that 23 that I have been -- number one, I was essentially 24 the chief safety officer for our consumer group for 25 three years and did a lot of work on talc safety.</p>

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<p>1 So many individuals and regular 2 employees, including security guards, asked me what 3 I think, and I tell them.</p> <p>4 Q What executives did you discuss the 5 Reuters article with? What Johnson and Johnson 6 executives?</p> <p>7 A Outside of our legal team, only the 8 individuals that I mentioned earlier today.</p> <p>9 Q That being, so we clear, we are not 10 talking about security guards?</p> <p>11 A We are talking Lynn Szczepaniak, Bobbette 12 Williams. Individuals in our quality organization. 13 Don Hicks, who is responsible for talc safety for 14 many years.</p> <p>15 Q Did you talk to any PR people?</p> <p>16 MR. SMITH: Objection.</p> <p>17 A I did talk to our communications people. They were asking for my help and advice.</p> <p>18 Q Who was that?</p> <p>19 A Ernie Knewitz.</p> <p>20 Q Ernie Knewitz works for Johnson and Johnson?</p> <p>21 A Yes.</p> <p>22 Q Were you involved in any way in shaping the message that was put forth by Johnson and 23 Johnson in response to the Reuters article?</p>	<p>1 school, Gordon Brown, Professor Pooley and Johnson 2 and Johnson, correct?</p> <p>3 A Yes.</p> <p>4 Q Now, 265. 265 is a report on the Johnson 5 and Johnson's Baby Powder that Gordon Brown 6 provided you, correct?</p> <p>7 A Yes.</p> <p>8 Q And that was the report that you gave to 9 the FDA, correct?</p> <p>10 A It looks to be, yes.</p> <p>11 Q And the methodology that Gordon Brown used 12 in analyzing the baby powder was X-ray diffraction, 13 correct?</p> <p>14 A Yes.</p> <p>15 Q And he concluded that there was no 16 evidence of chrysotile or tremolite found using that 17 technique, correct?</p> <p>18 A Yes.</p> <p>19 Q But you, Johnson and Johnson, knew that 20 the X-ray diffraction was not going to find 21 chrysotile under 2 or 3 percent, correct? We went 22 through that.</p> <p>23 A We did, but this is in 1972. So these are 24 early days in asbestos testing.</p> <p>25 Q Yes, Ma'am. And you also knew that the</p>
<p>1 MR. SMITH: Objection.</p> <p>2 A No. They asked me to fact check.</p> <p>3 Q Fact check what?</p> <p>4 A References to scientific literature, how 5 things were discussed to make sure that the language 6 was appropriate and scientifically correct.</p> <p>7 Q Who asked you to do that fact check?</p> <p>8 A Ernie.</p> <p>9 Q So we are clear, Ernie --</p> <p>10 A Knewitz.</p> <p>11 Q And his job specifically was what?</p> <p>12 A Communications.</p> <p>13 Q Did Johnson and Johnson actually hire outside 14 consultants to help them with this public relations?</p> <p>15 MR. SMITH: Objection.</p> <p>16 A I wouldn't know that.</p> <p>17 Q That was something we would have to ask Ernie Knewitz?</p> <p>18 A Correct.</p> <p>19 Q Just so the record is clear, going back to 20 the Lewin scenario and what you gave to the FDA, up 21 on the screen is a November 29, 1972 submission, 22 correct? That is what you have in front of you?</p> <p>23 A Yes.</p> <p>24 Q And again, we have McCrone, Colorado</p>	<p>1 x-ray diffraction was not going to find low levels of 2 tremolite, correct?</p> <p>3 A Yes.</p> <p>4 Q 35 is an October 27, 1972 report to 5 Johnson and Johnson from the Colorado School of 6 Mines, correct?</p> <p>7 A Yes.</p> <p>8 Q And that, again, was the report you gave 9 to the FDA, correct?</p> <p>10 A Yes.</p> <p>11 Q Again, the Colorado School of Mines used 12 X-ray diffraction as the testing method at the 13 request of Johnson and Johnson. That's what it 14 says, right?</p> <p>15 A No. X-ray diffraction step scanning, 16 which is a more sensitive X-ray diffraction.</p> <p>17 Q That's what was used?</p> <p>18 A Yes.</p> <p>19 Q And based upon the x-ray diffraction test, 20 the Colorado School of Mines didn't find any 21 chrysotile asbestos, correct?</p> <p>22 A They didn't find serpentine, so, yes, 23 chrysotile would fall into that category.</p> <p>24 Q They did not use the preconcentration method that they were recommending in performing</p>

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1 these tests, correct? 2 A Well, in a different context. They were 3 looking -- Lewin said there was 3 percent chrysotile 4 in there. So you would not need a concentration 5 method to detect that level of chrysotile. 6 Q You would need it if you wanted to go 7 lower than that. 8 A You would. 9 Q And they did not use the concentration 10 method in analyzing these samples, correct? 11 A Correct. 12 Q 461. Now, 461 is a subsequent submission 13 that Johnson and Johnson made to the FDA concerning 14 the Lewin samples. Is that fair? 15 A Yes. 16 Q Dated May 25, 1973? 17 A That is correct. 18 Q And that was by a Martin J. Borger (ph.) or 19 Burger? 20 A I don't know. However you say it is fine 21 with me. 22 Q What you used was X-ray diffraction, 23 correct? 24 A Yes. 25 Q And using X-ray diffraction, he didn't	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
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1 find any chrysotile, fair? 2 A That is correct. 3 Q Or tremolite? 4 A Or any number of, they list a whole bunch 5 of things he didn't find. 6 Q And he did not also apply the 7 concentration method, correct? 8 A Right. Again, it would be unnecessary 9 since Lewin was suggesting 2 and 3 percent of 10 chrysotile. 11 Q But if you wanted to find out if there was 12 any asbestos in there, you would use the 13 concentration method. You were just trying to 14 disprove Dr. Lewin. Is that what was going on? 15 A Actually, that was what was going on 16 because his methods were flawed. 17 MR. PLACITELLA: It is 3:58. I have 18 other things, but I think this is a place to stop 19 since we are about to change subjects. So why don't 20 we end for today and consult our calendars. 21 MR. SMITH: Fine. 22 THE VIDEOGRAPHER: The time is 23 approximately 3:59 p.m. This concludes today's 24 portion of the deposition. 25 (The deposition is adjourned.)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

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DOCUMENT LIST		
NO.	DESCRIPTION	PAGE
1 J&J-263	Report, Colorado School of Mines	142
2 J&J-45	J&J memo, 5/16/73	145
3 J&J-46	J&J memo, 6/4/73	147
4 J&J-58	Analysis of Talc, Dartmouth College, 3/74	159
5 J&J-352	J&J memo, 3/11/74	163
6 J&J-471	J&J memo, 11/24/76	166
7 J&J-369	J&J memo, 1975	167
8 J&J-353	Letter, J&J, 2/28/75	168
9 J&J-347	Report, 8/29/72	175
10 J&J-29	J&J memo, 8/24/72	176
11 J&J-40	J&J memo, 12/13/72	185
12 J&J-50	J&J memo, 7/31/73	188
13 J&J-38	Letter, J&J, 11/29/72	189
14 J&J-265	Report, 1972	196
15 J&J-35	Report, 10/27/72	197
16 J&J-461	J&J Submission to FDA, 5/25/73	198
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